

**Before the
U.S. Food and Drug Administration
Rockville, MD**

In the Matter Of:)	
)	
Brief Summary: Disclosing)	Docket No. 2004D-0042
Risk Information in)	
Consumer-Directed Print)	
Advertisements)	
)	
)	

COMMENTS OF PFIZER INC

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COMMENTS OF PFIZER INC

Pfizer Inc (“Pfizer”) submits these comments in continuing support of FDA’s efforts to revise its risk disclosure mandates for consumer-directed advertising. Pfizer appreciates that the agency recognizes the need to change its current regulatory approach. The goal of existing FDA regulations has been to give consumers exposed to direct-to-consumer (“DTC”) advertising immediate access to all of the risk information that the agency requires in professional labeling (subject, for broadcast advertising only, to limitations of time and cost). The new Draft “Brief Summary” Guidance on DTC risk disclosures in print advertisements (the “Draft Guidance”)¹ signals that FDA understands consumers absorb information differently from prescribers, even in the print medium. The agency has concluded that, for the sake of comprehensibility, it is reasonable to sacrifice some risk details in order to employ better communication techniques and avoid information overload.

¹ Pfizer’s comments here are limited to risk disclosures in traditional print advertisements and broadcast “spots.” Unless otherwise stated, we do not address risk disclosures in longer-form DTC communications such as product-specific websites and brochures.

Pfizer agrees that comprehensibility is critical for risk disclosures that can benefit consumers, and we appreciate the opportunity to work with FDA to determine whether the Draft Guidance's alternatives actually will enhance useful risk communication to laypersons. We also believe that the underlying objective for the disclosure mandates—which has ramifications for both the practical feasibility of the Draft Guidance and the legal sustainability of the agency's regulatory approach to DTC disclosures—must be reexamined.

In these comments, Pfizer first examines whether any of the Draft Guidance disclosure options will significantly enhance the comprehensibility of existing risk statements. This discussion also addresses how additional research could assist in that evaluation. We then turn to a more detailed reassessment of the underlying objectives, and constitutional significance, of a regulatory scheme clearly directed to enhancing the doctor/patient interaction stage of the treatment process. We believe that this analysis shows that the regulations set forth at 21 C.F.R. § 202.1(e), which were largely designed for prescriber-directed communications, are overbroad and constitutionally suspect in the context of consumer-directed messages. The Draft Guidance alternatives, while less detailed, still suffer from many of the same First Amendment infirmities.

Pfizer therefore urges FDA to articulate the objectives and reform the technique of its approach to DTC risk disclosures. In our view, the public health would be well served if FDA concluded that consumer-directed risk disclosures should (1) help a consumer to reasonably discuss a drug's benefits and risks with his or her doctor, and (2) prompt the consumer to alert the doctor to personal health information that should be factored into the treatment decision. By explicitly adopting this two-pronged goal, FDA would position itself well for crafting sustainable disclosure regulations.

SUMMARY

In announcing the release of the Draft Guidance, then-Commissioner Mark McClellan articulated FDA's growing understanding of how DTC advertising helps to support the public health: "The evidence shows that promotions directed to consumers can play a particularly important role in helping patients start a discussion with their health practitioner about many conditions that are often unrecognized and are under-treated in this country."² Dr. McClellan also noted the widespread consensus that the current "brief summary" approach to drug risk disclosures in print ads—*i.e.*, verbatim reprints of the advertised drug's FDA-approved label—"doesn't convey that information as effectively as it should to many consumers who find it too detailed and off-putting."³ He correctly recognized that

[t]his may be a case where "less is more" in terms of consumer understanding....

....

...Less is more for consumers because they can actually get more out of this information. The larger type, the clearer language, the focus on the more important risks that are a basis for further discussion with the health professional, and an appropriate basis is more beneficial to them in taking something away from the ads, rather than just skipping over a brief summary section as most consumers seem to do today.⁴

Pfizer agrees that the current disclosure regime is not contributing optimally to the public health.

It has fostered complex disclosures in traditional advertising when we have found, in practice,

² See Pfizer Transcript of FDA News Teleconference Announcing DTC Draft Guidances at 2 (Feb. 4, 2004) (attached hereto as Exhibit 1).

³ *Id* at 4.

⁴ *Id* at 3, 5. United States Surgeon General Richard H. Carmona also supports the "less is more" approach to DTC risk disclosures. See *id.* at 8-9; Press Release, U.S. Food and Drug Administration, New FDA Draft Guidances Aim to Improve Health Information (Feb. 4, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html> (quoting Surgeon General Carmona as saying, "The FDA's new guidance will help empower more patients with accurate information that they can understand, and encourage them to ask their doctors, nurses, and pharmacists questions. By closing the gap between what doctors know and what patients understand we can begin to help Americans take better care of themselves and improve their health.").

that simpler communication devices are more effective for laypeople.⁵ We also observe that the existing regulations have led to communications that both under-inform and, at least occasionally, over-deter consumers. They under-inform the many people who either simply skip over the brief summary or struggle to make sense of the risk information. They over-deter those who may be unnecessarily frightened by the disclosures and erroneously conclude that there is no point in contacting their doctors because the risks of treatment outweigh its benefits.

But eliminating a few of the disclosure mandates, as the Draft Guidance suggests, is not sufficient to reform FDA's requirements in a way that would be meaningful for consumers or constitutionally sustainable. Before FDA adopts a Final Guidance, it must seriously reexamine the underlying public health purposes that DTC risk disclosures can, and properly should, serve.

The overall purpose served by prescription drug advertising is no longer in doubt, thanks to the evidence FDA gathered in its recent Consumer-Directed Promotions review: the ads generally build awareness of disease conditions, suggest that drug therapy might be helpful, and motivate the consumer to contact a licensed prescriber. Under Pfizer's construct, consumer-directed risk disclosures, as one component of a complete DTC advertisement, should serve two subordinate purposes that support the overarching message: disclosures should (1) enable consumers to reasonably discuss a drug's benefits and risks with the prescriber before therapy begins, and (2) prompt consumers to alert their doctors to personal health information that would enhance the individual's safe and effective use of the drug.

⁵ For example, Pfizer has partnered with health-care entities such as the American Medical Association Foundation and the National Coalition for Literacy in the AskMe3 Initiative, which is designed to help encourage consumers to ask good questions of their health-care providers and to improve doctor-patient dialogue. *See* <http://www.askme3.org>. AskMe3 provides consumers with three simple and straightforward questions to ask their doctors that will enable them to better understand and act on health information related to their conditions. Pfizer does believe, however, in providing more detailed risk information to those consumers who are interested in that data—and we have found that other consumer-directed communications that do not fit the mold of traditional advertising, such as our website and patient-oriented brochures, are suitable vehicles for delivering risk information.

We firmly support the concept that our prescription drugs be administered with the informed consent of the consumer following an engaged doctor/patient dialogue. We therefore agree as a conceptual matter with the need for risk disclosures in DTC advertising. Indeed, we believe that it is in the best interest of our customers, as well as our own, for our DTC messages to communicate drug risk and benefit information in ways that consumers can understand.

Pfizer is concerned, however, about unprincipled risk disclosure mandates—meaning requirements that lack a guiding principle for reaching a concrete goal. FDA still has not articulated an explicit, achievable objective for consumer-directed disclosure requirements in the context of prescription drugs, *i.e.*, consumer protection in regard to products they can buy only after a “learned intermediary” has intervened and authorized the purchase. The agency has made vague allusions to its desire to better inform consumers about prescription drug risks, but it has not yet addressed how *much* better and to what *end* consumers should be informed.

A more precise definition of the government objective here is necessary for three reasons:

- First, it is difficult for drug manufacturers to make practical use of the Draft Guidance options unless they understand what end FDA seeks to achieve. The agency hopes its proposals afford advertisers scope to streamline disclosures to an amorphous degree in order to better inform consumers to an unspecified extent. But because advertising language and layout choices often raise ambiguities, advertisers need a more concrete end point to guide their selections.
- Second, a concrete government goal for DTC disclosures would produce an objective standard by which various disclosure options could be tested empirically. For various reasons, both FDA and advertisers need to know that DTC disclosures are actually succeeding—but options cannot be easily measured if there is no clear, achievable benchmark for “success.” In particular, a sweeping but vague goal of “better informing consumers” appears to offer no realistic end point.
- Third, the lack of a concrete goal puts FDA’s regulatory approach at legal risk. There is reason to doubt that “better informing consumers” provides a defensible constitutional foundation for mandatory impositions on manufacturers’ print advertising. By not concretely defining its goal for risk disclosure mandates, FDA leaves itself open to the logical implication that its objective is extensive consumer education that could justify nearly limitless requirements. The First Amendment, however, requires more precision of sustainable commercial speech mandates.

On the practical front, the Draft Guidance seeks to make good on the “less is more” concept by inviting advertisers to offer more selective disclosures in plainer language. But the basic options proposed so far—the “Highlights” section of proposed new professional labeling and some or all of the text of patient labeling—are messages developed in other contexts to serve other communicative goals. They are designed to speak to prescribers or to patients already under treatment; two audiences that differ from the DTC audience both in their ability to comprehend the information and intensity of their interest in it. In addition, neither Highlights nor patient labeling is universally available now, and they may not be for several years. Thus, manufacturers have no FDA-sanctioned text to adapt for risk disclosure purposes. The Draft Guidance then builds on these uncertain sources by requiring the disclosure of “all” of some types of risk information but less of other types. With one layer of uncertainty compounding another, manufacturers face risk of FDA enforcement for errors in selecting which risks to disclose.

Moreover, as FDA has acknowledged, its record contains essentially no factual evidence on the ability of typical consumers to understand and retain risk information presented in DTC advertising. This is true whether the disclosure language conforms to current rules, follows one of the Draft Guidance options, or represents any other possible alternative—such as the Federal Trade Commission’s earlier suggestion that FDA adapt for print advertisements the “adequate provision” concept used in broadcast commercials to provide access to more detailed risk data. Without at least some consumer testing to validate them, all of these alternatives could be criticized as arbitrary choices.

Pfizer is undertaking such research now because we believe that an empirical basis is essential, at a minimum, to evaluate the incremental benefit of options suggested in the Draft

Guidance. Additional research is necessary to determine how much risk information should be presented. For example, there is a need to determine what number of “most common nonserious adverse reactions” should be disclosed, or how placement and highlighting affects perception and retention. FDA’s illustrative disclosure, while a constructive effort to enhance the Draft Guidance, needs to reflect understandings gained from further research before it can operate most effectively as a consumer communications tool.

Finally, the Draft Guidance itself calls attention to the stringent requirements of 21 C.F.R. § 202.1(e), which impose risk disclosure obligations going far beyond those presented in the new enforcement policy statement. Even assuming that FDA will conform its enforcement activity to the boundaries of a final version of the Guidance, manufacturers still would remain at risk in state law actions where failure to comply with FDA regulations could be invoked.

Given these uncertainties and risks, manufacturers may determine that the safest course of action is to continue their current practices with respect to print risk disclosures—an outcome contemplated, albeit unfavorably, by the Draft Guidance. Preserving the *status quo ante* might minimize legal risk, but FDA has recognized properly that it will not best advance the public health. Therefore, in order to effectuate real change, the agency must move beyond the Draft Guidance and address the basic question of purpose: What can and should be achieved by DTC risk disclosures in print ads?

FDA should end doubt about the breadth of its goal by clarifying that the agency does not expect DTC ads to completely or perfectly inform consumers about all potentially relevant drug risks. Before it issues any Final Guidance, FDA should refocus its mandates to serve an achievable goal: risk disclosures should build upon the proven motivational impact of DTC ads by giving consumers enough information to ask reasonable questions of their doctors without

overwhelming laypersons with data that obscures key points or dissuades them from attempting to learn more about their health concerns and treatment options. By squarely casting its goal in this way, FDA will be positioned to devise regulations that directly and measurably advance the objective of improving the doctor/patient interaction that leads to proper treatment decisions without imposing additional and unnecessary burdens on manufacturer speech.

I. THE DRAFT “BRIEF SUMMARY” GUIDANCE IS A FIRST STEP TOWARD PRESENTING EFFECTIVE RISK DISCLOSURES IN CONSUMER-DIRECTED ADVERTISING

FDA recognizes that its current approach to satisfying the statutory “brief summary” requirement in DTC advertising is “less than optimal” for communicating risk information to consumers, and that the volume of the material, along with the format in which it is presented, “discourages its use and makes the information less comprehensible to consumers.”⁶ The evidence of record in the Consumer-Directed Promotions docket supports these observations.⁷ With respect to DTC advertising generally, FDA has a useful but still incomplete factual record concerning how consumers perceive and make use of information provided by such ads:

- Evidence shows that the key communicative power of advertising is to alert consumers to something potentially useful or desirable—particularly at the initial stage of the treatment path.⁸

⁶ FDA, *Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*, at lines 65-66, 69 (posted Feb. 4, 2004), available at <http://www.fda.gov/cder/guidance/5669dft.pdf> (hereinafter “Draft Guidance”).

⁷ See Comments of Pfizer Inc, Request for Comment on Consumer-Directed Promotion, Docket No. 03N-0344 (FDA filed Dec. 1, 2003) (hereinafter “Pfizer Consumer-Directed Promotions Comments”); Hearing Transcript, Direct-To-Consumer Promotion Public Meeting (Sept. 22, 2003), available at <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc>, (hereinafter “Hearing Transcript, Sept. 22, 2003”); Hearing Transcript, Direct-To-Consumer Promotion Public Meeting (Sept. 23, 2003), available at <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript2.doc>, (hereinafter “Hearing Transcript, Sept. 23, 2003”).

⁸ See Pfizer Consumer-Directed Promotions Comments at 11-13; Dr. Lewis G. Pringle, *Direct-To-Consumer Advertising: A Practical Communications Model and Commentary on Risk Communications*, Part One: 4-5, 8-10 (Jan. 5, 2004), submitted with Comments of the Coalition for Healthcare Communication, Request for Comment on Consumer-Directed Promotion, Docket No. 03N-0344 (FDA filed Jan. 14, 2004), available at

- Evidence reveals the well-recognized communicative weaknesses of advertising; it cannot successfully provide many details or a message custom-tailored to a particular individual's needs.⁹
- Evidence demonstrates that consumers generally make good use of the information they receive from DTC ads: They contact their physicians to discuss a health concern and potential treatment options, and they seek out more detailed information from other sources such as the Internet, magazines, brochures, and books.¹⁰

But FDA still has little to no evidence on whether, or how, consumers understand current risk disclosures or what use consumers make of that understanding—a key deficit with respect to the agency's efforts in this docket to improve upon the existing disclosure mandates. To make sound decisions here, FDA needs data on

- How many disclosures a consumer can actually absorb, and correctly interpret, from advertisements.
- Which types of disclosures may be best at motivating consumers to contact their doctors for more information and an individualized assessment—or which types of disclosures are likely to discourage them from even making the attempt.
- Which types of disclosures may be best at empowering consumers to pose useful questions or provide medically significant personal information to their doctors.
- Which types of disclosures may be best at motivating consumers to search out sources that provide more detailed information, such as drug manufacturer websites and brochures, other Internet sites, family medical guides, *etc.*

Given these data gaps, it should not be surprising that FDA's Draft Guidance does not provide ready solutions to the problem of advising consumers about drug risks in an appropriate and effective way. From the policy perspective, the Draft Guidance echoes an earlier agency initiative: FDA's call for more consumer-friendly text and format in print ads is in some respects

http://cohealthcom.org/content/jan04_fda_comments.htm (hereinafter "CHC/Pringle Consumer-Directed Promotions Comments").

⁹ See CHC/Pringle Consumer-Directed Promotions Comments at Part One: 9-11, 13-16, 26.

¹⁰ See Pfizer Consumer-Directed Promotions Comments at 14-17, 34-36 (summarizing data).

akin to the agency's 1997 Broadcast Guidance.¹¹ Both are products of FDA's struggles to address the practical limitations of time and space in effectively conveying a message to consumers through advertising. But neither incorporates a clear and achievable policy objective that can be satisfied by requirements empirically shown to further that objective.

Section II of these comments addresses the constitutional concerns raised by the DTC disclosure mandates, which are not overcome by the Draft Guidance's proposed elimination of some disclosure detail. Section I, however, focuses on very practical issues. Pfizer discusses below the problems of ambiguity that arise from importing disclosure mandates originally designed for other purposes into print disclosure. We also note that the ambiguities have serious collateral legal ramifications for manufacturers, who face not only questions about FDA enforcement action but also the prospect of state law actions based on claims of insufficient risk disclosure. We fear that these ambiguities are significant enough to dissuade many manufacturers from making use of FDA's attempt to partially streamline DTC disclosure mandates—effectively rendering the Draft Guidance a “non-guidance.” Such a result would frustrate the legitimate interests of all parties, including FDA, manufacturers, and consumers.

A. The Interests of FDA And Manufacturers in Crafting Effective Risk Disclosure Requirements Are Aligned, And FDA Should Approach The Task Of Revising The Guidance From This Perspective

Pfizer understands what the Draft Guidance represents: it signals FDA's awareness that its DTC disclosure regulations have serious shortcomings and its willingness to begin addressing them. In revising its mandates, FDA should understand that the fundamental interests of the government and manufacturers are aligned here. Both have reason to support the development of more effective consumer-directed risk disclosures. Pfizer urges FDA to make use of this

¹¹ FDA, *Guidance For Industry, Consumer-Directed Broadcast Advertisements* (Aug. 6, 1999), available at <http://www.fda.gov/cder/guidance/1804fnl.pdf> (finalizing 1997 draft guidance) (hereinafter “Broadcast Guidance”).

confluence of interests to gather more research data on how consumers perceive and react to risk information. That research will provide the necessary foundation upon which to craft better disclosures that can be empirically validated.

Although FDA's public health interest in risk disclosures is plain, manufacturers clearly also have good reasons—from public health and business perspectives—to favor the development and use of the best possible disclosures. Advancing the health of our customers is in everyone's interest. Manufacturers like Pfizer fully appreciate that drug risks, as well as benefits, need to be communicated effectively to doctors and to laypersons so that only appropriate patient populations obtain prescriptions for the products. Beyond the obvious desire to ensure that our drugs are used safely, manufacturers also have market-driven reasons to want to maintain corporate reputations as trustworthy sources of health products and information. It does not bolster a company's image if patients are disappointed by the results of drug therapy because they did not appreciate the product's limits.¹² Nor does it benefit a drug manufacturer to alienate prescribers by generating irrational consumer requests for drugs that cannot help them. Consequently, manufacturers have cause to welcome DTC risk disclosures that demonstrably assist patients and physicians to focus together on whether a particular drug is appropriate for a particular individual.

What remains lacking at this point is the empirical evidence demonstrating that one type of disclosure is more effective than another—as well as the basic question of what goal FDA and manufacturers can realistically expect to achieve through DTC advertising disclosures. The discussion in Section II explains why clear identification of the ultimate objective is critical to

¹² Moreover, testimony in FDA's Consumer-Directed Promotions docket suggested that consumers have more confidence in DTC ads when they include some risk information. *See* Hearing Transcript, Sept. 23, 2003 at 101-104.

the constitutional viability of FDA's disclosure regulations. But Pfizer is not waiting for that question to be resolved before embarking on some initial, consumer-focused research. As discussed in more detail in Section I.B.3 below, we have begun an extensive consumer communications research effort based on our understanding of the options presented in the Draft Guidance. We urge the agency to encourage both public- and private-sector entities to work with FDA in undertaking additional consumer-focused studies to provide more insight on the complex issues here before the agency finalizes the Guidance.

B. The Options For Risk Disclosure Presented In The Draft Guidance Are Not Yet Viable Alternatives To The Current “Brief Summary” Format

The Draft Guidance presents two basic alternatives to the current practice of printing the consumer-unfriendly professional labeling to satisfy DTC risk disclosure mandates: the reprint of a modified “Highlights” designed for professional labeling or the reprint of modified patient labeling designed to provide instructions for actual usage of the drug. If a manufacturer were to employ either option, FDA would exercise its enforcement discretion by refraining from taking action against an ad, even though its disclosures did not meet all the particulars of the codified rules.

These options have some initial appeal—they do result in somewhat shorter disclosures than the traditional brief summary. But as the discussion below explains, although the relative brevity of the options is helpful, brevity alone does not mean that they necessarily will work better to alert consumers to risks that they should discuss with their doctors. Indeed, FDA has no record to demonstrate which of any number of possible options might work best. The Draft Guidance, which uses preexisting formats designed for other purposes, raises unintended complications. In particular, it leaves the creators of DTC advertising with little guidance or

predictability to help them navigate the inevitable difficulties over content and language choices for real ads.

Implementing the proposed options also could delay development of research-tested methods for achieving what should be, in Pfizer's view, the two related goals for DTC disclosures: alerting consumers to (1) reasonably assess the risk/benefit balance with their doctors and (2) remind their physicians about individual health considerations that should be considered in the mix. FDA acknowledges in the Draft Guidance that it has "not evaluated how presenting the information in different formats affects consumer comprehension," and that much remains to be learned before a Final Guidance is developed.¹³ Given this admission, FDA's selection of the two alternatives offered in the Draft Guidance could be criticized as arbitrary. Other available alternatives might just as well have been proposed, such as the Federal Trade Commission's suggestion that FDA adapt the "adequate provision" concept used with broadcast ads to print advertisements.¹⁴ This is not to say that the FTC option is any better than the two that FDA has proposed. All are equally untested.

Finally, it must be noted that although the Draft Guidance proffers two alternatives for risk disclosures, the Guidance also specifies that use of either requires disclosure of exactly the same information—"all" contraindications, "all" warnings, "major" precautions that include "serious" adverse drug experiences, and "the 3-5 most common nonserious adverse reactions."¹⁵ This calls into question whether the two options are simply distinctions without a difference.

¹³ Draft Guidance at lines 275-277.

¹⁴ Comments of the Federal Trade Commission, Request for Comment on Consumer-Directed Promotion, Docket No. 03N-0344, at 21-25 (FDA filed Dec. 1, 2003), *available at* <http://www.ftc.gov/be/v040002text.pdf> (hereinafter "FTC Consumer-Directed Promotions Comments").

¹⁵ Draft Guidance at lines 171-177, 193-199, 216-222.

1. **The Highlights section, which has the advantage of a briefer format, was developed for communication with physicians**

As one alternative for satisfying the brief summary requirement, the Draft Guidance proposes that manufacturers try to adapt the information that would appear in the Highlights section of FDA-approved professional labeling.¹⁶ Several problems are inherent in this option. First, the Highlights section is designed to speak to the needs of professionals, not consumers. Second, there are no FDA-approved Highlights upon which manufacturers can yet draw. And although the Highlights format is relatively short, more than brevity is required in starting to redesign effective consumer-directed disclosures.

The agency first proposed creation of the Highlights section in 2000 in an effort to reduce medical errors frequently made by physicians when writing prescriptions.¹⁷ The concept was part of a larger effort to revise professional labeling. The proposed new regulation was designed to “make it easier for health care practitioners to access, read, and use information in prescription drug labeling and... enhance the safe and effective use of prescription drug products.”¹⁸ FDA explains that the Highlights section “would consist of selected information that *practitioners most commonly refer to and view as most important* from specific sections in the comprehensive prescribing information.”¹⁹

¹⁶ Draft Guidance at lines 206-253.

¹⁷ Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082 (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201) (hereinafter “Proposed Physician Labeling Rule”). See also Press Release, U.S. Department of Health and Human Services, Physician Labeling Proposal (Dec. 21, 2000), available at <http://www.fda.gov/bbs/topics/NEWS/NEW00745.html>.

¹⁸ Proposed Physician Labeling Rule at 81082.

¹⁹ *Id.* at 81085 (emphasis added).

Plainly, then, information provided in a Highlights section is selected based on prescribers' habits, and not based on any evaluation of what consumers may need. Although FDA has not yet clearly articulated its goal for DTC risk disclosures, the purpose must certainly differ from that which drove the design of the Highlights section. FDA cannot assume that what a professional with years of medical training might consider most important is the same information that a layperson might absorb or value. In several instances, of course, they may be congruent—but the agency currently lacks data to prove the point one way or the other. FDA acknowledges that the actual language of the proposed Highlights section is unlikely to be comprehensible to consumers and so urges manufacturers to translate it into plain English.²⁰ Such translation obviously would be necessary, but so too is a more fundamental consideration of what substantive messages consumers can effectively “take away” from advertising risk disclosures. Many of the Highlights disclosures do not appear necessary to spur consumers to engage their physician in individualized assessment of a drug's risks and benefits.²¹

Beyond the different audiences for which Highlights and DTC risk disclosures are intended is an even more intractable problem: FDA-approved Highlights language does not yet

²⁰ Draft Guidance at lines 244-253.

²¹ The proposed regulation requires the Highlights section to include: an indication of whether the product has been approved in the United States for less than three years and contains a new molecular entity (NME) or a new biological product, a new combination of active ingredients, is indicated for a new population, is administered by a new route, or uses a novel drug delivery system; an indication of whether there have been recent substantive labeling changes for the drug; information on the proper usage of the drug; information on the dosage and administration of the drug; information on how the drug is supplied; and information on how to report adverse reactions to the drug. *See Proposed Physician Labeling Rule at 81088 - 81090.* FDA acknowledges in its Draft Guidance that this information should be omitted from the risk disclosures made to consumers in DTC advertising, and provides an example of how to redraft a Highlights section written for communication with professionals into a consumer-directed risk communication device. Draft Guidance at lines 229-242; FDA, *Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule) Translated in Consumer-Friendly Language and Formatted for Use in Consumer-Directed Advertisement* (posted Feb. 4, 2004), available at <http://www.fda.gov/cder/guidance/5669high2.pdf> (hereinafter “Fictional Highlights Example”). Even if some or all of this detail were dropped from the consumer-directed disclosure, it is plain that the source material was designed to serve other purposes.

exist. The proposed professional labeling rule has been pending for nearly four years, and there is no indication when the rule might become final. Once the Highlights rule finally does go into effect, the specific language used in the professional labeling will be subject to FDA pre-approval. Today, however, manufacturers have no assurance that what they might think would satisfy the as-yet nonexistent Highlights mandates would in fact meet FDA's requirements; so far there are only hypothetical models, but no "real world" example, upon which to draw.

Even if and when the Highlights rule is adopted, such sections will not be available for all drugs. The proposed regulation notes that Highlights will be required only for products with applications "pending at the time of the effective date of the final rule, products for which such applications are submitted on or after the effective date of the final rule, and products with such applications that were approved up to and including 5 years before the effective date of the final rule."²² FDA has explained that it proposes to limit the Highlights mandate because it believes that physicians are less likely to consult product labeling when prescribing an older drug.²³ While this may be a valid observation with respect to doctors' need for drug information, it plainly is not valid with respect to laypersons. Their needs are highly unlikely to vary depending on the age of a drug that is, in any event, new to the consumer if not the marketplace. But for older drugs, manufacturers apparently will never have an FDA-approved Highlights from which to extract appropriate DTC disclosures.

The Draft Guidance therefore asks manufacturers to create a hypothetical communication for professionals and then extrapolate from it certain information that might be appropriate for consumer risk disclosures. As discussed below in Section I.B.4, an option that builds one

²² Proposed Physician Labeling Rule at 81098.

²³ *Id.*

uncertainty upon another is not likely to entice manufacturers to abandon the existing brief summary approach.

2. **Patient labeling, which is targeted to laypeople, was developed to communicate appropriate usage instructions to patients who already have obtained a prescription**

In addition to the Highlights option, the Draft Guidance offers manufacturers the choice of modeling alternative risk disclosures on FDA-approved patient labeling.²⁴ There also are inherent problems with this option. Once again, the difficulties begin with the fact that the original message was designed to serve a different purpose. The audience does consist of laypersons, but they are not consumers being alerted at the beginning of the treatment path to a potential health issue and treatment option—instead, the audience for patient labeling has moved beyond the diagnosis and prescription stage to actual drug usage. Consequently, these two groups of consumers plainly have different needs for, and likely differing degrees of interest in, drug risk information. FDA should not assume, absent empirical evidence, that consumer needs are always the same simply because the audience is not composed of educated professionals. At the very least, FDA needs data to substantiate the assumption that the risk information appropriate for consumers before they have even been diagnosed is identical to that appropriate for patients under treatment.

In fact, FDA in other proceedings has implicitly decided that even consumers well along the treatment path have varying information needs, which depend upon the drug at issue. This is demonstrated by the broad array of patient labeling formats that FDA has approved: Information for the Patient, Medication Guides, Patient Information, or Patient Package Inserts (“PPIs”).²⁵

²⁴ Draft Guidance at lines 123-204.

²⁵ *See id.* at lines 126-127.

The risk information presented across these diverse formats is not uniform. For example, specific FDA regulations require PPIs for certain contraceptives and estrogen products that are tailored to the characteristics of the drug at issue.²⁶ (FDA once considered making PPIs mandatory for all prescription drugs but later rejected that proposal, stating that the mandate seemed to operate more to inhibit, than encourage, manufacturers to develop consumer-friendly drug information vehicles.²⁷) Medication Guides, on the other hand, can be required on a case-by-case basis when the FDA determines that a particular prescription drug product, including biological products, “pose a serious and significant public health concern requiring distribution of FDA-approved patient information.”²⁸ FDA’s website indicates approximately 20 drugs and biologics for which Medication Guides have been required and developed.²⁹

This drug-specific approach to patient labeling seems well justified by the different characteristics of individual drugs. But it spotlights another problem for adapting patient labeling as DTC risk disclosures. Patient labeling is not mandatory for all drug products—and thus, as with the professionally oriented Highlights, there are no FDA-sanctioned models

²⁶ See 21 C.F.R. § 310.501; 21 C.F.R. § 310.515. For example, the PPI requirement for oral contraceptives requires a boxed warning concerning the increased risks associated with cigarette smoking and oral contraceptive use. 21 C.F.R. § 310.501(c)(4).

²⁷ See Prescription Drug Products; Patient Package Inserts Requirements, 45 Fed. Reg. 60754 (Sept. 12, 1980); Prescription Drug Products; Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39147, 39150 (Sept. 7, 1982) (noting, “The most limiting aspect of the program, however, appears to stem from its mandatory nature. Its existence seems to have been responsible for the lack of some private sector initiatives which have grown measurably since the agency indicated that withdrawal of the rule was contemplated.”).

²⁸ 21 C.F.R. § 208.1(a). Patient labeling can be required if FDA “determines that one or more of the following circumstances exists: (1) The drug product is one for which patient labeling could help prevent serious adverse effect. (2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients’ decision to use, or to continue to use, the product. (3) The drug product is important to health and patient adherence to directions for use is crucial to the drug’s effectiveness.” *Id.* § 208.1(c).

²⁹ See Center for Drug Evaluation and Research, Office of Drug Safety, *Patient Labeling and Risk Communication*, (updated Apr. 8, 2004), available at <http://www.fda.gov/cder/Offices/ODS/labeling.htm>.

available for adaptation in many instances. Yet the very case-specific issues presented by many drugs means that manufacturers likely would be reluctant to attempt to craft patient-labeling-style risk disclosures for any product for which actual patient labeling does not already exist. As discussed below in Section I.B.4, the risks for manufacturers who make wrong guesses appear high, while the cost of continuing with the *status quo ante* appears low.

3. **Rather than requiring uniform disclosures, FDA should gather empirical data to show that a particular disclosure is optimally effective**

The discussion above points out that there is not yet evidence to justify any particular set of disclosures or formats for presenting it. Pfizer therefore urges FDA to step back from the Draft Guidance and reevaluate its approach to the issue. The first step should be to marshal at least some facts to support the chosen disclosures, which must include evidence demonstrating that the mandated speech does advance a concrete and achievable objective.

FDA already concedes that it has little or no such data,³⁰ and expects to be modifying the Guidance before it become final. Indeed, the document also suggests that the agency does not yet know even what risks should be disclosed, much less how those disclosures should be worded. The Draft Guidance purports to offer at least two distinct alternatives to the traditional brief summary disclosure, but FDA undermines the distinction by requiring that each option provide the identical number and identical type of disclosures—*e.g.*, “all” warnings, “major” precautions, “3-5” common but nonserious side effects.³¹ The Draft Guidance does not explain why this mandatory overlay applies uniformly to each of the putative options. Nor does the document offer additional insights that would help manufacturers determine which precautions

³⁰ Draft Guidance at lines 275-277.

³¹ *Id.* at lines 171-177, 193-199, 216-222.

are major or which common but nonserious side effects should be disclosed. The overlay does imply, however, that FDA is simply proposing a slightly reduced version of the current brief summary as the new disclosure paradigm and is not attempting to more fundamentally reconsider the purpose and operation of its DTC risk disclosure mandates.

Pfizer urges the agency to embark on an evidence-based—and admittedly more complex—effort to craft sustainable disclosure requirements. Because Pfizer recognizes that the task must begin with the gathering of more empirical data than FDA currently has on hand, we already are responding by initiating a study of certain print disclosures options.

Our current plans call for consumer communications testing of ads about two drugs approved to treat different health conditions. For each condition, independent researchers engaged by Pfizer will present a representative sample of the target audience with up to seven different disclosure options. The alternatives will be based on what Pfizer understands might be the new flexibility under the Draft Guidance. Our objective will be to determine which option(s) appears to hold the most promise for helping consumers grasp key risk concepts without deterring them from consulting their doctors for an individualized assessment. We hope to have data on hand by the end of 2004 and will be pleased to share that information with FDA.

Although our choice of language to be tested is hampered somewhat by the Guidance's ambiguities, we hope to learn more about how certain specific disclosure options may affect a consumer's motivation to pursue a consultation with a physician. It is not hard to imagine that some options might overwhelm consumers with so much detail that they cannot retain it or, worse, that they misinterpret some risks and develop exaggerated fears that prevent them from

seeking treatment.³² It seems plain to us that even the most reasonable proposals warrant consumer testing before implementation.

Pfizer wishes to be clear about what our 2004 research effort can, and cannot, teach us. We hope that the study will identify a range of improved disclosure options for print ads. We also anticipate gaining some insight on the incremental role that these disclosures play in communicating benefits and risks while spurring consumers to contact their doctors and initiate a richer discussion.³³ This new research is not designed, however, to identify the one best approach to risk disclosures. Nor will it be able to reveal the optimum amount of information or specific content that will lead to the best health-care decision-making.³⁴ While this notion and

³² See, e.g., Hearing Transcript, Sept. 22, 2003, at 229-230 (Dr. Angela V. Hausman of the University of Texas discussing the results of a study in which patients surveyed indicated that disclosures of risks and side effects in DTC ads were “too honest”. Some patients reported that they were convinced to stop taking a medication because of the potential side effects presented in DTC advertising.). In surveys conduct by the FDA, 47% of general practitioners and 42% of specialists agreed that DTC advertisements create anxiety in their patients regarding the potential side effects of drug treatments. Kathryn Aikin, Ph.D., *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, at slide 54 (Sept. 22, 2003) (citing *FDA Patient Survey* (2002)), available at <http://www.fda.gov/cder/ddmac/aikin/index.htm>.

³³ Our legal analysis of the data also will be informed by our understanding of the First Amendment limits constraining FDA. In particular, the legal question of what may be “enough” risk information is shaped by the Constitution’s predisposition against compelled disclosures that do not directly advance a legitimate governmental objective. See *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 559 (1985); *United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001). In the commercial speech context, this means that if two disclosure options with differing levels of detail are shown to be equally effective at furthering the objective, the government can only mandate the less extensively detailed option. See, e.g., *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). This does not mean, of course, that the advertiser may not choose on its own to provide details beyond the governmentally mandated level.

³⁴ Future research beyond Pfizer’s current effort may well determine, for example, that certain patient-focused disclosures about contraindications—such as “Tell your doctor if you have Condition X or are already taking Drug Y”—are easier for consumers to retain than even a short list of side effects. Evidence already shows that long lists of drug risks do not effectively inform consumers; FDA itself recognizes that “exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks.” Draft Guidance at lines 70-71. Literature from the health literacy field also indicates that consumers are unable to properly weigh statements regarding the probability of risk. Eric J. Johnson, *Rediscovering Risk*, J. Pub. Pol’y & Marketing (forthcoming Spring 2004), available at <http://bear.cba.ufl.edu/centers/jppm/dmp/johnson.pdf>; Jonathan Baron, *Cognitive Biases, Cognitive Limits, and Risk Communication*, J. Pub. Pol’y & Marketing (forthcoming Spring 2004), available at <http://bear.cba.ufl.edu/centers/jppm/dmp/baron.pdf>. What remains lacking is a better understanding of where the list should be cut off in drug ads, how any remaining risks or warnings should be worded, and what use consumers would make of directives to find more detailed risk information elsewhere.

others have some theoretical plausibility, we take as a caution the unintended outcome of other recent and well-meaning risk reform efforts.³⁵ Our current research effort will not analyze the relationship between DTC advertising disclosures and the availability of more detailed risk information in other consumer-directed communications, such as manufacturer brochures, websites, and patient labeling. Finally, it will not probe the very critical process by which consumers make trade-offs in seeking health-care treatments. These are questions that deserve further empirical study by FDA and others, however, before the agency finalizes the Guidance.³⁶

4. **Because the Draft Guidance does not give manufacturers certainty in developing risk disclosures that comply with FDA regulations, manufacturers are likely to continue using the brief summary**

Even if adapting the Highlights section or patient labeling were an appropriate solution to crafting effective DTC risk disclosures, the Draft Guidance does not provide manufacturers with sufficiently clear direction on how to use the models. Without better assurances that they have perceived what FDA wants—and therefore can be deemed compliant with FDA enforcement policy—manufacturers may disregard the new disclosure options.

One concrete illustration of the practical dilemmas posed by the Draft Guidance is the patient labeling option. The Guidance would allow a manufacturer to offer disclosures that either reproduce FDA-approved patient labeling in its entirety or “as modified to omit less

³⁵ As Pfizer has noted before, the European Commission recently developed a set of risk guidelines that grouped side effect incidence into verbal probability ranges—*e.g.*, very common, common, uncommon, rare, and very rare. See Pfizer Consumer-Directed Promotions Comments at 53 (citing Diane C. Berry, et al., *Patients’ Understanding of Risk Associated with Medication Use: Impact of European Commission Guidelines and Other Risk Scales*, 26 Drug Safety 1-11 (2003)). Although this tiered approach to risk warning was meant to better inform consumers, it worked instead to frighten and confuse them: research data indicated that laypersons would be less likely to take the medication because they perceived the risks as significantly higher than they were.

³⁶ Pfizer is also committed to working with FDA to determine the best way to utilize help-seeking ads in order to maximize the motivational power of DTC. Pfizer’s interests are thus aligned with FDA on this issue. Pfizer believes the role of help-seeking ads should be critically evaluated so that they will be able to have the greatest possible impact in spurring consumers to discuss their health conditions with their doctors.

important risk information.”³⁷ As noted above, there are various types of patient labeling, and they are not consistent in terms of risk information content. The agency acknowledges this, stating:

Not all FDA-approved patient labeling describes a product’s most serious risks and its less serious, but most frequently occurring, adverse reactions. Some FDA-approved patient labeling primarily gives instructions for use.... Other FDA-approved patient labeling focuses primarily on a single important warning. Where FDA-approved patient labeling has a narrow focus and does not provide information on the product’s most serious risks and its less serious, but most frequently occurring, adverse reactions, FDA believes this labeling would not be suitable for conveying risk information in a consumer-directed print advertisement.³⁸

In short, manufacturers are left to make a judgment call as to whether their patient labeling—if it exists at all—contains the type of risk information that FDA contemplates as an appropriate baseline for adaptation as DTC risk disclosures. The manufacturer then must decide what to trim, or what to add, to satisfy the uniform overlay requirements that the Guidance specifies. There would be at least two, and possibly three, levels of “guesstimating” involved in the effort. In the end, manufacturers could not be sure that FDA would be satisfied with the result and, at the same time, there would be no basis for knowing that the effort would actually help consumers “focus on the most important risk information for the drug.”³⁹

These layers of uncertainty mean that manufacturers have little incentive to seriously attempt to implement the new options. They may well continue to abide by the current brief summary requirement, even though all interested parties here—FDA, manufacturers, and consumers—agree that the brief summary is a poor vehicle for effectively communicating

³⁷ Draft Guidance at line 96.

³⁸ *Id.* at lines 143-150.

³⁹ *Id.* at lines 155-156.

relevant risk information.⁴⁰ From a business perspective, the brief summary option has the advantage of regulatory certainty, imposes no unpredictable costs, and—as discussed below—carries considerable benefits with respect to available defenses against state law-based actions challenging the adequacy of particular risk disclosures.

C. Adherence To The Guidance Options for DTC Risk Disclosures Would Not Provide Manufacturers Sufficient Protection From Legal Challenge Under State Law Statutory or Tort Theories

As FDA well knows, plaintiffs in various fora have sued prescription drug manufacturers based, at least in part, on allegedly inadequate warnings given in DTC advertising.⁴¹ Whether the theory of the case is grounded in so-called “little FTC” state advertising and competition statutes or in state tort law, the result can be the same—manufacturers may be obligated to bear significant financial penalties if they lose. In successfully defending themselves against such challenges, manufacturers have frequently pointed out that their ads comply with FDA’s extensive regulations and have called upon courts to recognize that these federal mandates preempt any contrary state laws.⁴² Accordingly, many manufacturers likely will be loath to abandon the brief summary style of DTC risk disclosure until FDA adopts new alternatives that will work equally well as defenses against suits based in state law.

⁴⁰ See Pfizer Consumer-Directed Promotions Comments at 49, n.146 (summarizing opinions on the brief summary); Draft Guidance at lines 65-73.

⁴¹ See, e.g., *Dowhal v. Smithkline Beecham Consumer Healthcare*, Docket No. S109306, 2004 Cal. LEXIS 3040 (Cal. Apr. 15, 2004); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001), *aff’d* 358 F.3d 659 (9th Cir. 2004); *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174 (N.J. Super. Ct. App. Div. 2003).

⁴² See, e.g., *Dowhal*, 2004 Cal. LEXIS 3040, at *32-*33; *Schering-Plough Corp.*, 842 A.2d at 177; *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1251 (N.J. 1999).

Congress has the power to preempt state law under the Supremacy Clause of the Constitution.⁴³ Thus, a state law that conflicts with a federal statute is “without effect.”⁴⁴ Federal preemption generally occurs in one of three situations, two of which are relevant here: (1) where Congress implies preemption of state law by occupying a field exclusively, either by enacting so pervasive a scheme of federal regulation that it can be inferred that Congress has left no room for further state regulation or by regulating in an area in which the federal interest is so dominant that the federal scheme can be assumed to preempt state laws on the same subject; or (2) to the extent that there is an actual conflict between state law and federal law, for example where it is impossible for a party to comply with both or where the state law would impede Congress from accomplishing the objectives set forth in its laws.⁴⁵

Although preemption power rests in the hands of Congress, there is one circumstance in which agency regulations also have preemptive effect: Rules promulgated under an explicit delegation of authority from federal lawmakers also preempt state law where the latter directly conflicts with the federal regulation.⁴⁶ FDA’s rules under Section 502(n) of the Food, Drugs and Cosmetics Act (“FDCA”) fit this model. The federal statute requires that prescription drug advertisements contain a “true statement” of “information in brief summary relating to side effects, contraindications, and effectiveness,” but expressly delegates to FDA the power to define

⁴³ U.S. Const. art. VI, cl. 2 (stating that the “Laws of the United States ... shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.”).

⁴⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

⁴⁵ See *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990); see also *Cipollone*, 505 U.S. at 516.

⁴⁶ See Charles H. Koch, Jr., *Administrative Law and Practice* § 4.24[1] (2d ed. 1997).

the limits of the mandates.⁴⁷ As a result, the FDA regulations at 21 C.F.R. § 202.1(e) are not considered mere “interpretive” rules but rather are deemed “legislative” rules and accorded the force of law.⁴⁸ Accordingly, they have been cited as preempting state law claims against drug manufacturers.⁴⁹

The Draft Guidance does not supersede FDA’s codified regulations. Those legislative rules remain in effect, even if FDA employs its discretion in choosing not to strictly enforce all elements of the codified mandates. Therefore, adherence to one of the Draft Guidance’s risk disclosure options—even if a manufacturer could correctly discern FDA’s “current thinking” on appropriate risk disclosures—might not serve as a defense against state-law claims. To the contrary, a plaintiff pressing such a suit might well contend that a manufacturer who employed a Draft Guidance disclosure option was, in fact, violating federal law.

To eliminate this disincentive against the use of alternative disclosure options that would better serve consumer needs, FDA should prepare to act decisively in its Final Guidance to enhance protections for compliant advertisers against state-law disclosure challenges. Specifically, as further discussed in Section II.B, FDA should state explicitly that its Final Guidance represents the maximum imposition that can be legally supported at this time by a legitimate government interest. FDA should further announce that it will be incorporating a

⁴⁷ 21 U.S.C. § 352(n)(3) (prescription drug advertisements will be deemed to be misbranded unless they include a true statement of “information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title....”).

⁴⁸ See Koch, *supra* note 46, § 4.11[2] (explaining, “Legislative rules are rules made pursuant to delegated authority to make rules. Because they are an extension of a legislative act, they have the force of law and are subject to very limited judicial review....”).

⁴⁹ See, e.g., *Schering-Plough Corp.*, 842 A.2d at 177 (noting that “the wording of the ads, to the extent that it is subject to FDA oversight, see 21 C.F.R. § 202.1, is ... not actionable” under a state consumer fraud statute).

constitutional limitation in revised legislative rules under 21 C.F.R. § 202.1(e) and expressly stating its intent to make those rules preemptive.

II. FDA MUST TAKE FURTHER STEPS TO ENSURE THE CONSTITUTIONALITY OF ITS RISK DISCLOSURE MANDATES

The Draft Guidance reveals that FDA perceives the constitutional framework under which its advertising regulations must operate. This is the agency's first concrete response to the legal issues presented in the 2002 First Amendment Inquiry and to the factual data presented in the 2003 Consumer-Directed Promotions proceeding.⁵⁰ The First Amendment Inquiry revealed that FDA may impose limits on DTC advertisements only where the restrictions (1) prevent false or deceptive communications, or (2) advance a bona fide public health purpose that cannot adequately be achieved by less speech-restrictive regulations. The Consumer-Directed Promotions proceeding established that that DTC advertising yields substantial benefits in the health care system and cannot be shown to be "inherently deceptive" even if lacking the full range of disclosures designed for doctors to use in making treatment decisions.

Although the Draft Guidance is an improvement over the codified rules, the new enforcement policy still leaves unsettled the legal sustainability of FDA's approach to risk disclosure regulation. As noted above, the Draft Guidance simply trims existing rules to somewhat limit the volume of mandatory disclosures. The new effort has not involved a fundamental reevaluation of the legitimate purpose of risk disclosures in consumer ads, an assessment of how those legitimate objectives should affect the clarity of the ad message, or any

⁵⁰ Pfizer incorporates by reference in this proceeding the comments it earlier submitted in these two dockets. *See* Comments of Pfizer Inc, Request for Comment on First Amendment Issues, Docket No. 02N-0209 (FDA filed Sept. 13, 2002) (hereinafter "Pfizer First Amendment Comments"); Pfizer Consumer-Directed Promotions Comments.

considerations of whether other regulated messages might be better vehicles to deliver detailed health information.

Moreover, because the Draft Guidance is simply a policy statement on the agency's current approach to enforcement, it does not remedy the legal weaknesses of the codified rules. To address the long-term need for a constitutionally sustainable regulatory scheme, FDA should craft a Final Guidance that ensures that enforcement remains within the ambit of the First Amendment while the agency undertakes the required rulemaking procedures.

A. While Welcome, The Greater Flexibility Afforded Under The Draft Guidance Still Falls Short Of Satisfying The First Amendment

Pfizer already has indicated that FDA's DTC advertising rules have serious constitutional weaknesses. Our First Amendment Comments point out that the constitutional analysis "is driven principally by one simple but profound point: because consumers are, by definition, shielded by learned intermediaries in the selection and use of prescription drugs, it is not essential for DTC advertisements to outline to consumers what each and every particular risk of a drug might be. What is important is for DTC advertisements to alert consumers that such risks exist and that consumers should discuss them with their doctors."⁵¹ Given the facts now on record, FDA's power to compel speech—in the form of mandatory risk disclosures—is considerably constrained by the First Amendment's insistence that the compelled speech demonstrably serve a legitimate governmental purpose.⁵²

This constitutional concern applies to both the codified rules and the Draft Guidance. Although the latter would impose slightly fewer speech mandates, there still is reason to question the constitutional sustainability of the alternatives presented in that document. The analysis in

⁵¹ Pfizer First Amendment Comments at 141-142.

⁵² *Id.* at 59-60.

the following subsections applies the four-pronged *Central Hudson* test,⁵³ to the Draft Guidance options and to the regulations that still lurk beneath them. The discussion below reveals vulnerabilities under several prongs of the analysis: (1) FDA currently lacks evidence to show that DTC ads concerning approved uses are either false or misleading absent any particular number or type of disclosures; (2) FDA has not clearly identified a substantial and achievable goal that disclosures are intended to serve; (3) FDA currently lacks evidence to demonstrate that its disclosure mandates in particular (as opposed to DTC ad messages in full) directly advance a legitimate goal; and (4) FDA cannot demonstrate that its disclosure mandates are sufficiently tailored to serve their identified purpose without unnecessarily impinging on advertisers' speech rights. The agency can and should address these vulnerabilities before it issues a Final Guidance on DTC risk disclosures in print ads.

1. **FDA cannot sustain a claim that DTC advertisements are false or misleading in the absence of either the full set of disclosures mandated by its rules or the somewhat reduced set of disclosures set forth in the Draft Guidance**

DTC ads that promote FDA-approved claims are not *per se* “false or misleading” to consumers absent all risk disclosures, and the agency to its credit appears to have abandoned this notion as a broad contention.⁵⁴ It would be extremely difficult to successfully contend that a

⁵³ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

⁵⁴ In a related vein, the Draft Help-Seeking Guidance identifies so-called “bookend” advertisements—consisting of a reminder ad in close physical or temporal proximity to a help-seeking ad—as problematic. See FDA, *Guidance for Industry, “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms*, at lines 199-232 (posted Feb 4, 2004), available at <http://www.fda.gov/cder/guidance/6019dft.doc>. FDA has indicated that if two such ads also are “perceptually similar” (in terms of graphic design or repetitive usage of other characteristics), the two “effectively constitute an advertisement that communicates a product’s indications and efficacy for a certain medical condition with providing risk or other information.” *Id.* at lines 195, 201-202. Pfizer agrees that a close nexus between two such ads in time or space may give rise to legitimate questions about whether the ads should be subject to product claim regulation.

FDA should clarify, however, that other combinations of ads do not raise the bookend issue. In particular, the agency should make plain that a help-seeking ad in close proximity to a full product ad is not improper. The logic behind FDA’s objections to bookending is not *just* that help-seeking and reminder ads “are presented in a manner

factually true but arguably incomplete DTC ad is either false or misleading, given the unique—and statutorily mandated—role of the learned intermediary as gatekeeper over consumer drug usage.

It is plain why the doctor’s presence in the “commercial transaction” alters the typical assessment of whether an advertisement is false or misleading. Ads traditionally target a mass audience and concern products over which the consumer has total purchasing control. It therefore follows that assertions made in traditional advertising, when subjected to a *Central Hudson* analysis, are reviewed for truthfulness under a generalized “objective” or “reasonable” consumer standard.⁵⁵ But the “truth” of a prescription drug claim for a particular individual requires one-on-one analysis with a doctor, who is charged with marshaling his or her professional expertise and knowledge of the patient’s case history in determining whether the drug is likely to be effective in meeting that particular individual’s needs. If there were no need for tailoring drug therapy to the individual, Congress would not have recognized, through FDCA, the need for professional intervention.

These truths about mass-market advertising and individualized diagnosis and therapy are not in tension. To the contrary, they are a slightly more complex manifestation of a commonplace in American life: consumers understand the difference between a mass-market advertisement and the individual assessments they make in actually deciding to acquire and use the advertised product. There is no evidence that consumers are inherently confused or misled by the distinction between an advertisement about a prescription drug and a consultation with a

that causes their messages to be linked together by the audience,” *id.* at lines 203-204, but that *neither* part brings risk disclosures or other mandated information to the mix. In contrast, FDA’s logic compels the conclusion that if a fully compliant product ad were “linked together” with a help-seeking ad, the fully compliant risk disclosures of the former are necessarily brought into the mix. Consequently, there is no logical basis for concern about possible evasion of full product advertising rules.

⁵⁵ See *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

doctor about the advertised drug. Accordingly, FDA’s authority under the Constitution to compel disclosures in DTC ads hinges squarely on whether the agency can specifically show that the advertisements would be “potentially misleading” absent particular disclosures or that the disclosures would serve some “substantial” goal other than safeguarding against false or misleading speech.⁵⁶

2. FDA is legally required to explicitly identify a substantial and achievable goal for its risk disclosure mandates

To build a legally sustainable regulatory regime for its DTC risk disclosure mandates, FDA must begin by plainly articulating the goal(s) it seeks to achieve through these speech restrictions. The agency still is not officially on the record in this regard, which puts its regulatory regime at legal risk—because the government goal is the foundation upon which the remainder of the commercial speech analysis rests. Under *Central Hudson*, courts will scrutinize the government’s claimed interest for legitimacy and, if the interest is deemed “substantial” enough, will use it as the baseline by which to measure the constitutionality of the restraint.⁵⁷

As noted above, then-Commissioner McClellan has said that FDA recognizes that there are practical limits to the purposes the agency may seek to achieve through consumer-directed disclosures. He also pointed directly to the key, and demonstrably achievable, objective that DTC ads can serve: “the evidence shows that promotions directed to consumers can play a particularly important role in helping patients start a discussion with their health

⁵⁶ See, e.g., *In re R. M. J.*, 455 U.S. 191, 203 (1982) (“States may not place an absolute prohibition on ... potentially misleading information ... if the information also may be presented in a way that is not deceptive.”); *Peel v. Attorney Registration & Disciplinary Comm’n*, 496 U.S. 91, 109 (1990) (“Even if we assume that petitioner’s letterhead may be potentially misleading to some consumers, that potential does not satisfy the State’s heavy burden of justifying a categorical prohibition against the dissemination of accurate factual information to the public) (citation omitted); *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999) (“FDA may not restrict speech based on its perception that the speech could, may, or might mislead.”).

⁵⁷ See, e.g., *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

practitioner....”⁵⁸ These conclusions also appropriately reflect the legal distinction that Congress has made, through FDCA, between the different roles of the consumer and licensed health-care professional concerning access to prescription drugs.

But the Draft Guidance itself does not acknowledge the distinction or its impact on the agency’s objectives for DTC risk disclosures. This leaves the regulatory regime vulnerable to constitutional challenge as having unrealistic goals that cannot justify excessive speech restrictions—either because the goals cannot be reached or because their success cannot be measured.⁵⁹

FDA has made general references to DTC’s role in “educating” consumers but has left dangling the question of what purpose the DTC risk disclosure “education” is expected to achieve. The agency has not claimed that a “perfect” DTC risk disclosure could educate consumers about a prescription drug to the point that they could forego consultation with a doctor. But neither has FDA identified what realistic end point it has in mind for this consumer education effort. In fact, the existing advertising regulations—which date back decades—still largely fail to distinguish between the needs and abilities of the two distinct audiences to make use of the information. It is this aspect of the outdated regulations, obviously, that has fed the widespread industry practice of reprinting official labeling as the required brief summary.⁶⁰

An achievable, consumer-oriented goal for DTC risk disclosures is a necessary element of a legally sound regulatory scheme. If a First Amendment challenge were ever lodged against

⁵⁸ See Ex. 1 at 2.

⁵⁹ See, e.g., *Zauderer*, 471 U.S. at 651; *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 193 (1999) (holding that a regulation cannot be sustained if there is “little chance” that the restriction will advance the State’s goal); *Edenfield*, 507 U.S. at 770-771; *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 566 (2001) (ill-considered goal not legally “substantial”).

⁶⁰ This compelled speech was a serious waste of resources that might have been used to disseminate more and/or better messages to consumers.

the existing rules or the Draft Guidance enforcement policies, a court could well take FDA's vague assertions to their logical extreme: "better educating consumers" means "educating consumers to the fullest possible degree." That, in turn, theoretically could support mandated disgorgement of pages of risk data with every advertisement. Such a result—even when cast only as a hypothetical debating point—is likely to disquiet any court that takes serious stock of the First Amendment considerations at issue here.

To overcome this weakness in its regulations, FDA must confront the legal ramifications of the target audience's interest and ability to absorb information: When the audience is laypersons rather than licensed prescribers, there is no "substantial government interest" in compelling detailed disclosures that consumers can neither evaluate nor directly act upon without the assistance of a learned intermediary.⁶¹ Pfizer urges FDA to plainly state that its ultimate objective is to foster disclosures that help to motivate consumers to (1) reasonably discuss with their doctors the risk/benefit issues involved with treatment options, and (2) remind their doctors about the individual's particular health issues that should be weighed in making a treatment choice.

This goal is legally sustainable and reflects reality. It recognizes that a DTC ad's major impact occurs at the beginning of the treatment path, when the message helps consumers identify

⁶¹ Nearly half of American adults have difficulty understanding medical terms and directions. *See Risks Rise With Failure To Decode Health Terms*, Washington Post, Apr. 9, 2004, at A8 ("Comprehending medicine's jargon is difficult for even the most educated laymen. It is almost impossible for millions who cannot read well, are not fluent in English, or have vision or cognitive problems caused by aging.... Now the prestigious Institute of Medicine has put a number on how many people have 'limited health literacy' - 90 million adults. They have problems following instructions on drug labels, interpreting hospital consent forms, even understanding a doctor's diagnosis and instructions."). *See also, e.g.*, Vice Admiral Richard H. Carmona, United States Surgeon General, Remarks at the Meeting of the National Library of Medicine Board of Regents (Feb. 10, 2004), available at http://www.surgeongeneral.gov/news/speeches/nlm_lowlit_02102004.htm (noting a recent study of English-speaking patients in public hospitals that "revealed that one-third were unable to read basic health materials." Twenty-six percent of patients surveyed could not read their appointment slips; 42% did not understand the labels on their prescription bottles.) (citing M.V. Williams, *et al.*, *Inadequate Functional Health Literacy Among Patients at Two Public Hospitals*, 274 JAMA 1677 (Dec. 6, 1995)).

health conditions that can be treated by a doctor.⁶² It supports existing law by encouraging the interaction that must take place between a patient and prescriber before prescription drug treatment can begin. Furthermore, by implication it places the drug benefit/risk assessment where it belongs: within the doctor/patient interaction, where the physician’s professional knowledge and experience with the patient’s individual case history can be brought to bear on the decision-making process. Neither DTC ads in the mass media nor any other manufacturer-generated communication could possibly substitute for the individualized risk analysis that doctors and patients undertake during medical consultation.⁶³ It is at that point in the process, not at the beginning, where comprehensive risk information may be pertinent—and likely would be best understood by the consumer.⁶⁴

Establishing a sustainable policy goal for risk disclosures does not answer the question of just how many disclosures should be included in DTC ads, but it does put FDA on the right path to making that determination. By understanding the limited purposes it can seek to achieve with its risk disclosure mandates, the agency could fashion DTC advertising rules and policies that actually serve consumers better. FDA could consciously strive to enhance doctor/patient dialogue by equipping the patient to (1) understand that the advertised drug has some risks that need to be evaluated by, and discussed with, the prescriber, and (2) disclose to the prescriber facts (*e.g.*, existing health conditions) that are important to the risk/benefit analysis. Revised risk

⁶² DTC advertising may also provide collateral benefits by reminding treated patients to continue with their drug therapy, but there is nothing in the record of the First Amendment or Consumer-Directed Promotion proceedings to suggest that these benefits are the principal objectives of “full disclosure” ads.

⁶³ To clarify, as noted *supra* note 5, Pfizer believes in providing detailed risk information to interested consumers in formats that work well for communicating detail—such as, *e.g.*, our extensive website pages, printed brochures, etc.

⁶⁴ *Cf.* CHC/Pringle Consumer-Directed Promotions Comments at Part One: 15, 25-26 (noting that “[e]ven though mass media advertising may be quite well suited to creating general awareness of the overall risk of Rx communications, it simply is *not* suited to accomplish the stated objective of rendering in its objects the desired levels of detailed and complex understanding.” (emphasis in original)).

disclosure mandates might also properly recognize that more comprehensive risk information is available to interested consumers through other communication outlets along the treatment path.⁶⁵

3. **With a clear and realistic goal in mind, FDA can craft regulations that demonstrably advance it in a direct and measurable manner**

By articulating a realistic goal for its DTC risk disclosure mandates, FDA sets the groundwork for the next critical step in crafting a defensible regulatory scheme. The First Amendment requires that commercial speech restrictions “directly advance” the identified government interest.⁶⁶ The “direct advancement” requirement has significant consequences here: FDA must be able to show that its disclosure mandates “will *in fact* alleviate [the asserted harm] to a material degree.”⁶⁷ Simply identifying laudable public health goals is not sufficient to shield extensive disclosure mandates from legal challenge. Even if the compelled speech is framed in colloquial terms, FDA still needs some facts to show that the disclosures are achieving their purpose: “A regulation cannot be sustained if it ‘provides *only ineffective or remote support* for the government’s purpose,’ ... or if there is ‘*little chance*’ that the restriction will *advance the State’s goal*....”⁶⁸

Many of the intricate risk disclosure rules codified at 21 C.F.R. § 202.1(e) cannot satisfy this legal standard within the context of DTC advertisements. Requirements designed

⁶⁵ For example, as suggested by the FTC Comments in the Consumer-Directed Promotions proceeding, FDA should seriously consider the utility of including a revised “adequate provision” construct to the regulations governing DTC print advertising. *See* FTC Consumer-Directed Promotions Comments, at 21-25. *See also supra* note 14 and accompanying text. Directing interested consumers to full risk details provided on the manufacturer’s website or brochures, for example, would help take better advantage of the communicative impact of traditional advertising and the communicative depth inherent in other formats.

⁶⁶ *Cent. Hudson*, 447 U.S. at 566.

⁶⁷ *Edenfield*, 507 U.S. at 771 (emphasis added).

⁶⁸ *Lorillard*, 533 U.S. at 566 (emphasis added) (internal citations omitted).

approximately four decades ago to produce technically detailed disclosures addressing prescribers' needs cannot "directly advance" the general goal of informing consumers, who cannot make useful sense of the information. And if consumers have great difficulty comprehending the disclosures, there is no reason to believe that the compelled speech can serve the ultimate objective of motivating consumers to engage their doctors in dialogue about health issues and treatment options. FDA's recognition of the rules' vulnerability on this prong of *Central Hudson* obviously spurred development of the Draft Guidance.⁶⁹

There is reason to doubt, however, that the new enforcement approach goes far enough to withstand a First Amendment challenge. Although FDA has gathered a considerable amount of empirical research on the general impact of DTC advertisements—which shows that the ads deliver public health benefits—there still is almost no data focused on the risk disclosure component of those ads. FDA therefore cannot yet justify the inclusion of every element required under the disclosure options provided within the Draft Guidance.⁷⁰

Even FDA's "Consumer-Friendly Language" example raises constitutional questions, in part because of its sheer length. At this point, FDA has no way of knowing whether this full-page disclosure would encourage or discourage consumers who could benefit from consulting a doctor on the health condition and treatment option at issue. The page provides approximately 15 different disclosures, some of which are duplicative.⁷¹ How much can a consumer be expected to remember from a 15-point disclosure statement? Does this level of detail bury facts

⁶⁹ Draft Guidance at lines 57-73.

⁷⁰ Indeed, to Pfizer's knowledge, there is no specific evidence on record at the agency to bolster FDA's decision to streamline certain disclosures. For example, it is not clear why FDA has decided that adverse reaction reporting may be limited to "the 3-5 most common non-serious" ones—as opposed to any other number.

⁷¹ For example, the point that the fictional "Ocracephalose" must be used in conjunction with other diabetes medications is noted in both the opening "indications" passage and the warnings section. *See* Fictional Highlights Example.

that are more important than others? Is the page so overwhelming that consumers may skip over it completely? Are all of these details necessary to prompt the consumer to initiate a productive doctor/patient dialogue? Which points should consumers be prompted to raise in that dialogue? Which points are effectively addressed at other stages along the treatment path, such as during the medical consultation or at the point of purchase?

In short, FDA has yet to confront another constraint on its regulatory power here: the limitations of comprehensibility. Although the Draft Guidance is a distinct improvement over the strict application of the codified rules, the agency still lacks evidence to justify the modest cut it has made here. The First Amendment does not permit the government to compel speech if it is not germane to the ultimate goal.⁷² Offering “mere speculation or conjecture” to connect all of the 15 disclosures to the goal of encouraging appropriate doctor/patient dialogue will not be sufficient to meet the government’s legal burden.⁷³

Furthermore, the record is not blank in this regard. To sustain all 15 disclosures, FDA would have to rebut evidence submitted in the Consumer-Directed Promotion proceeding by the Coalition for Healthcare Communication. A supporting commentary by Dr. Lewis G. Pringle, a marketing professor with decades of academic and professional experience, reviews the well-accepted research in that field concerning advertising’s strength as a communicative vehicle in creating initial awareness—and its weaknesses as an effective method of delivering detailed information, particularly if the subject requires individualized assessments.⁷⁴ Dr. Pringle notes that:

⁷² See, e.g., *Zauderer*, 471 U.S. at 651.

⁷³ *Edenfield*, 507 U.S. at 770.

⁷⁴ See CHC/Pringle Consumer-Directed Promotions Comments at Part One: 4-6, 9-11, 13-16.

[I]t is always tempting to add another copy point to the commercial.... The objective problem ... is that there *is* a cost ... that has been recognized by advertising professionals [for decades]. [T]he problem is *not* one of simple diminishing returns to scale.... The problem is much more severe. The problem is that, ultimately, the *message* is lost. Not a diminishing part of it. All of it.⁷⁵

This information overload cost is not limited to broadcast commercials; print ads are vulnerable in their own way.⁷⁶ In addition to the CHC/Pringle submission, other participants in that proceeding raised similar points.⁷⁷

FDA appears to understand the general concept because it is incorporated within the agency's Strategic Action Plan of August 2003: "FDA also knows that information can at times be confusing to some consumers, and too much information can provide a cacophony of data that can obscure the most important facts."⁷⁸ The Draft Guidance, however, offers no indication that FDA has assessed the communicative impact of the extensive disclosures that it still would require in print ads. The translation of professional argot into everyday English obviously is helpful, but it is not fully responsive to the information overload problem.

The Draft Guidance's approach to risk disclosures suggests that FDA has not yet conceptually distinguished its authority to regulate drug labeling from its authority to regulate DTC advertising. The new approach to enforcement of the print disclosure rules, like the codified regulations themselves, requires a detailed distillation of much of the labeling

⁷⁵ CHC/Pringle Consumer-Directed Promotions Comments at Part One: 11 (emphasis in the original).

⁷⁶ *Id.* at Introduction: 5-6.

⁷⁷ During FDA's September 2003 hearing on consumer-directed promotions, Dr. Ruth Day suggested that a generalized "all drugs have potential benefits and risks" warning could be more effective than a detailed recitation of specifics in building awareness of the need to weigh risks and benefits in consultation with a health care provider. *See* Hearing Transcript, Sept. 22, 2003 at 249.

⁷⁸ FDA, *Empowering Consumers: Improving Health Through Better Information*, FDA Strategic Action Plan at 17-18 (Aug. 2003), available at <http://www.fda.gov/oc/mcclellan/FDAstrategicPlan.pdf>.

information. For historical reasons, this admixture may be understandable, but that does not make it legally defensible now.⁷⁹ As Pfizer has explained earlier, FDA has considerably more power to mandate labeling information than it does to mandate advertising content.⁸⁰ The legal distinction flows logically from the functional differences in purpose between the two types of communication.

What Pfizer has called “operative labeling”—the label as approved by FDA under 21 U.S.C. § 355(b)(1)(F) and 21 C.F.R. § 314.50—is designed for the purpose of assisting prescribers in making prescription decisions and in directing the patient to use the drug safely. Given labeling’s purpose, FDA enjoys great power under the First Amendment to require disclosure of all warnings, contraindications, precautions, and adverse reactions. At this point on the treatment path—when the physician has diagnosed the patient and is considering treatment options—such details should be taken into account. The operative labeling is a direct, and not overly burdensome, means of assuring that the professional prescriber has readily available data on which he or she can rely.⁸¹

The same is not the case, however, for DTC advertising. This speech is not designed to inform prescriber’s decision-making process or substitute for a physician’s directions on proper use of the product. Both of those steps come later on the treatment path. DTC ads serve a lawful and beneficial purpose at an earlier point on that path: They seek to spur a consumer to *begin* the dialogue with the physician about a condition and treatment option. Once that conversation has started, other types of communications—including the FDA-approved operative labeling—help

⁷⁹ Pfizer First Amendment Comments at 110-115.

⁸⁰ *See id.* at 127-129, 146 (comparing “rational basis” analysis applicable to labeling with heightened scrutiny applicable to commercial speech).

⁸¹ *See* Pfizer First Amendment Comments at 74-79.

to enrich the discussion and thereby “directly advance” the goal of achieving the best possible therapy decisions for the individual patient. Still later on the treatment path, FDA-approved consumer materials such as the PPI may “directly advance” the goal of ensuring patient compliance with the treatment regimen by ensuring that the individual has written instructions that provide detailed dosage directions, warnings, contraindications, and so forth.

But the fact that FDA can justify detailed disclosures at one stage on the treatment path does not mean it has power to justify the same set of disclosures at every stage.⁸² The agency is not free to disregard the communicative purpose of advertising or the constitutional protection that truthful and nonmisleading commercial speech enjoys.⁸³ To Pfizer’s knowledge, FDA has no data indicating that a consumer needs to know “all” warnings and contraindications associated with a drug in order to begin a useful conversation with a doctor about the product or the condition it treats. Accordingly, the full list of compelled disclosures required under the Draft Guidance do not necessarily “directly advance” the government’s legitimate interest in regulating the advertising.

Recognizing this limitation would not strip FDA of power to police DTC ads: the agency retains considerable authority under *Central Hudson* to prohibit false or misleading advertisements.⁸⁴ As Pfizer has stated previously, we believe that this would extend at a minimum to generalized warnings that “all drugs have risks” and that consumers must consult a doctor in order to assess whether the product is suitable for the individual. It may mean that other disclosures in DTC advertising could be justified as well. For example, FDA might be able

⁸² To the contrary, as discussed in the next section, because FDA already has required detailed disclosures at other points along the treatment path, it has eliminated the justification for duplicating them in DTC advertising.

⁸³ See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-367 (2002).

⁸⁴ Consequently, most of FDA’s advertising rules do not suffer from the same constitutional infirmity that infects 21 C.F.R. § 202.1(e).

to demonstrate that alerting consumers to contraindications—in the form of statements such as “Tell your doctor if you have X condition or are taking Y medication”—makes an important contribution to the initiation of doctor/patient dialogue. The agency also might be able to justify the need for certain warnings or additional risk disclosures on a case-by-case basis. In any event, before FDA may constitutionally compel any specific disclosures, it must amass some evidence that the disclosures actually serve to help motivate consumers to initiate a risk/benefit dialogue with their doctors.

4. **Having a clear and achievable goal also will support FDA in sufficiently tailoring the scope of its disclosure mandates to meet constitutional requirements**

The codified rules governing DTC risk disclosure plainly are not “narrowly tailored,” as the First Amendment requires, to meet substantial and achievable government objectives. FDA has conceded as much by releasing the Draft Guidance. However, even those slightly relaxed disclosure mandates appear vulnerable to challenge—in part because FDA has not been explicit about the precise goal that the agency seeks to meet. Without a clear objective, FDA would find it exceedingly difficult to show that it had sufficiently tailored its regulations to achieve that goal without unnecessarily impinging on advertiser’s speech rights. In addition, existence of other readily available sources of information about prescription drug risks (some of which FDA already regulates) limits the agency’s authority to mandate essentially duplicative disclosures in every regulated message about a drug.

The final prong of the *Central Hudson* analysis requires the agency to tailor its disclosure mandates so that they are “not more extensive than is necessary to serve” its articulated and legitimate goal.⁸⁵ This means that FDA must “‘carefully calculat[e]’ the costs and benefits

⁸⁵ See *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 434 (1993).

associated with the burden on speech imposed” by the regulation at issue.⁸⁶ While the fit between the end and means need not be “perfect,”⁸⁷ a demonstrable degree of precision is required.⁸⁸ Courts will evaluate that precision by considering the availability of other regulatory alternatives:

A regulation need not be “absolutely the least severe that will achieve the desired end,” but if there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the “fit” between ends and means is reasonable.⁸⁹

FDA advertising regulations have foundered on this very prong before. The Supreme Court in *Western States* struck down a statutory prohibition on pharmacist advertisements concerning particular “compounded” drugs, holding that FDA failed to prove that the restrictions “are not more extensive than is necessary to serve [its asserted] interests.”⁹⁰ The majority opinion pointedly noted that the agency apparently had disregarded the Court’s teaching that “if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”⁹¹

The DTC risk disclosure mandates—whether the full panoply laid out in codified rules or the slightly relaxed requirements set forth in the Draft Guidance—appear to suffer from the same flaws. First, because FDA has not clearly identified its ultimate goal for the disclosures, it is

⁸⁶ *Discovery Network, Inc.*, 507 U.S. at 417; *accord Lorillard*, 533 U.S. at 561.

⁸⁷ *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

⁸⁸ Arguably, the Court has interpreted this prong more strictly in the last decade than it did in earlier cases. *Compare Fox*, 492 U.S. at 476-81 with *Western States*, 535 U.S. at 371-373.

⁸⁹ *Discovery Network, Inc.*, 507 U.S. at 418 n.13 (citation omitted); *see also, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490-91 (1995) (invalidating regulation prohibiting disclosure of alcohol content on beer labeling because temperance goal could be served by, *e.g.*, directly limiting the alcohol content of beer or banning only the emphasis on high alcohol content in advertising).

⁹⁰ *Western States*, 535 U.S. at 371 (citation omitted).

⁹¹ *Id.*

hard to measure whether the mandates are directly advancing the objective in a manner that is not unduly burdensome. If the goal truly were to “better educate consumers” to an unspecified end point, the agency theoretically could contend that every possible disclosure mandate would serve that sweeping goal. As noted above, courts quite likely would reject this position because it would leave FDA with essentially limitless discretion.

FDA’s jurisdiction over speech plainly does not extend that far.⁹² Consumer “education” through advertising falls within FDA’s purview only because it can advance an objective directly within the agency’s governing statute: the safe usage of prescription drugs. The regulatory focus therefore should be targeted on the doctor/patient dialogue in which drug risks and benefits relevant to the individual patient are discussed. As noted above, this focus should make FDA’s task of creating defensible rules easier as a practical matter because the agency can devise a standard for measuring the rules’ effectiveness and a basis for calculating how extensive they need to be to succeed.

The final prong of *Central Hudson* requires that FDA consider whether there are “numerous and obvious less-burdensome alternatives” to its chosen restrictions on commercial speech. While the Draft Guidance options do pare down on some disclosures mandated by the codified regulations, FDA has not built a record that shows that it has seriously considered other options.⁹³ First Amendment precedent does not require that FDA envision all possible alternatives, but the agency could well be taken to task for failing to consider an option that it already employs for broadcast ads: the “adequate provision” mechanism. The agency has determined that directing TV viewers or radio listeners to the manufacturer’s website or a toll-

⁹² See *Wash. Legal Found.*, 56 F. Supp. 2d at 86; *Western States*, 535 U.S. at 371-377.

⁹³ See, e.g., *Western States*, 535 U.S. at 372-373.

free information number works sufficiently well to advise interested laypeople more fully about a drug's risks and benefits.⁹⁴ As of yet, FDA has no data on the record to show that this same mechanism would not work as well for readers of print ads.⁹⁵

Furthermore, a reviewing court would likely note that DTC ads are only one of several FDA-regulated information sources concerning prescription drug risks.⁹⁶ The first, of course, remains the drug's approved labeling; FDCA itself gives the prescribing physician the primary responsibility to impart information about drug risks and benefits to consumers by counseling individual patients on how to use the products. In addition, FDA already has taken steps—by developing the PPI—to ensure that consumers who have been given access to a prescription drug have on-the-spot directives to guide safe usage.

Finally, *Central Hudson* requires FDA to take some note of the many information sources outside of the agency's control that also provide consumers with truthful data about prescription drugs. These include publications and Internet sites developed by medical entities, patient groups, insurers, and others. The fact that the same information is available from unregulated sources calls into question the need for extensively regulating one particular class of speaker.⁹⁷

Faced with the wealth of available information and prospect for greater use of alternative, less burdensome, disclosure options upon which the agency already relies, FDA likely would be hard-pressed to prove that the full panoply of DTC risk disclosure mandates for print advertising

⁹⁴ Although the adequate provision mechanism at this time allows manufacturers to opt to use a print ad for full disclosures, Pfizer is unaware of any data showing that print ads are better suited to this purpose—or are more accessible to consumers—than are detailed website pages, mailed brochures or telephone conversations.

⁹⁵ The average print ad may be able to provide more information than the average broadcast ad, but there is evidence on record that the ability of any advertisement to effectively communicate detailed risk data is limited. *See* CHC/Pringle Consumer-Directed Promotions Comments at Part One: 10, 13, 26, 30.

⁹⁶ *See, e.g., Western States*, 535 U.S. at 371-373.

⁹⁷ *See, e.g., Greater New Orleans*, 527 U.S. at 190-191.

is necessary to spark appropriate doctor/patient dialogue about drug risks. Pfizer recognizes that FDA faces a significant line-drawing challenge in determining which disclosures meet the *Central Hudson* test—one that may require a multi-year effort and new research data to satisfy. We stand ready to assist FDA develop constitutionally defensible rules.

B. The Final Guidance Should Set Forth Constitutionally Sustainable Enforcement Policies That Will Apply During The Pendency Of Formal Rulemaking Action

It is plain that FDA recognizes that its current advertising regulations do not address the needs and capabilities of consumers. The codified rules compel advertisers to engage in—and subsidize—speech that does not help a lay audience but nonetheless functions as a prerequisite to manufacturers’ right to engage in constitutionally protected speech of their own choosing. Although the First Amendment affords FDA some scope to compel disclosures, that authority does not extend so far as to require pointless speech.⁹⁸

The Draft Guidance seems to embody an agency compromise between, on the one hand, the best possible response to consumers’ health information needs and, on the other hand, the disclosure requirements set forth in the FDCA and the agency’s 40-year-old implementing regulations.⁹⁹ As discussed above, however, the compromise approach still represents a significant burden on speech that lacks a demonstrable connection to real public health benefits.

⁹⁸ See *Zauderer*, 471 U.S. at 651. As Thomas Abrams, Director of FDA’s Division of Drug Marketing, Advertising and Communication noted in a humorous aside during the agency’s September 2003 hearing on consumer-directed promotions, the roots of today’s DTC regulation date to a period when the regulated information was limited to the official drug labeling and was, in fact, *intended* to be incomprehensible to laypersons. Hearing Transcript, Sept. 22, 2003, at 12-13. Should FDA fail to update its regulations to demonstrably meet consumer needs, this history likely would be weighed against the agency in any constitutional analysis of the rules or agency enforcement policies.

⁹⁹ Section 502(n) of the FDCA was enacted as part of the Kefauver-Harris Drug Amendments of 1962. Within a year, FDA adopted its initial proposal for implementing rules, which called in somewhat general fashion for “a showing of those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement and any other use or uses for which the dosage form advertised is commonly prescribed.” See *Drugs; Statement of Ingredients; Prescription-Drug Advertisements*, 28 Fed. Reg. 6375, 6376 (June 20, 1963). The more detailed language now largely codified as 21 C.F.R. § 202.1(e) was proposed in 1967

Moreover, the Draft Guidance is simply an advisory on current agency officials' intended exercise of their enforcement discretion. It does not, as a legal matter, obviate the need for revising the underlying regulations to meet constitutional requirements. If there were any doubt as to whether the First Amendment applied to FDA's advertising regulations when they were adopted more than a generation ago, *Western States* put that doubt to rest.¹⁰⁰ Constitutional constraints now require that FDA determine the degree to which its existing advertising rules are overbroad and revise them accordingly.

Furthermore, FDA should act to protect the regular functioning of its enforcement efforts while the rulemaking is pending. The agency should call now for new or existing research data as to how much risk information consumers can usefully absorb from advertising and then fashion a Final Guidance that responds to the empirical evidence. Taking this step also will help FDA ward off potentially disruptive legal challenges while the agency updates the formal rules.

In addition, FDA should declare plainly in the Final Guidance that its revised enforcement policies represent the maximum extent to which the agency may constitutionally impose disclosure mandates on DTC advertisements. It also should announce that the same constitutional limitation will be brought to bear on a revised version of the restraints at 21 C.F.R. § 202.1(e) and expressly state FDA's intent to make those rules preemptive.

The text of FDCA is no bar to substantive revision of the codified advertising rules. Section 502(n) of the organic statute requires only a "brief summary" "relating to" side effects—and therefore affords the agency substantial flexibility with respect to the content of the required

and finally adopted two years later. See Prescription Drug Advertising and Labeling Regulations, 32 Fed. Reg. 7533 (May 23, 1967) (to be codified as 21 C.F.R. pt. 1); Prescription-Drug Advertisements: Confirmation of Effective Date of Order Acting on Objections, 34 Fed. Reg. 11357 (July 9, 1969).

¹⁰⁰ *Western States*, 535 U.S. at 366-368.

“summary.” That section also allows the agency to amend its implementing rules under the procedures set forth in Section 701(e) of the Act, 21 U.S.C. § 371(e).¹⁰¹ As noted above, the key substantive passages of those rules took effect in the 1960s, long before DTC advertising emerged in its modern form. Although the regulatory history of the rule now codified as 21 C.F.R. § 202.1(e) is sparse, what exists indicates that FDA’s focus at the time was on professional advertising.¹⁰² This record dovetails with actual advertising practices up until approximately 1985, when FDA finally concluded that it would not take punitive action against DTC ads that replicated all of the detailed disclosures required in professional advertising.¹⁰³

FDA plainly has authority to determine that the key provisions of Section 202.1(e) do not fully satisfy the needs of consumers, who—as the agency recognizes—lack “the technical background to understand this information.”¹⁰⁴ Although amending the codified rules requires

¹⁰¹ For example, the “fair balance” construct—which has led to rote, tit-for-tat lists of benefits and risks in many DTC ads—appears only in the regulations, not the statute. FDA would have ample authority to revise the regulations to clarify that the key concern is not to present consumers with an equally weighted “balancing” of risks and benefits but rather to give laypersons a “fair” presentation of the drug’s efficacy and limitations.

¹⁰² The legislative history of Section 502(n) reveals that Congress, in giving FDA authority over prescription drug ads, was focused on alleged abuses in ads targeted to physicians and other professionals. See Thomas A. Hayes, M.D., *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 Food & Drug L.J. 57, 61 (1996). The thin regulatory history suggests the same. See *Reminder Labeling and Reminder Advertisements for Prescription Drugs*, 40 Fed. Reg. 58794, 58796 (Dec. 18, 1975) (“The intent of... reminder advertisements under § 202.1 is to bring to the attention of the medical practitioner the availability of a drug product by calling attention to the name of the drug product.”) (emphasis added).

¹⁰³ As Pfizer detailed in its First Amendment Comments, FDA effectively repressed DTC advertising until 1982 by virtue of its silence on the subject, which the pharmaceutical community took to signify the agency’s opposition to such ads. Statements made by the then-Commissioner in that year encouraged the industry to begin planning DTC ad campaigns, which FDA stopped by imposing a temporary moratorium that lasted for two years. The agency’s approach to mandatory disclosures continued to operate to keep broadcast ads—other than help-seeking or reminder ads—off the air until 1997, when FDA approved the current relaxation of the disclosure mandates for TV and radio spots. See Pfizer First Amendment Comments at 111-112 (citing, e.g., Wayne L. Pines, *FDA Advertising and Promotional Manual*, ¶ 441 (Thompson Publishing Group 2001); See Arthur Hull Hayes, Jr., Comm’r of Food and Drugs, *Summarizing the State of Pharmaceutical Advertising*, Address Before the Pharmaceutical Advertising Council (1982), referenced in Wayne L. Pines, *A History and Perspective on DTC Promotion*, 54 Food & Drug L.J. 489, 492 (1999); David A. Kessler & Wayne L. Pines, *The Federal Regulation of Prescription Drug Advertising*, 264 JAMA 2409, 2412 (1990)).

¹⁰⁴ Draft Guidance at line 67.

adherence to procedures that may extend the time needed for the formal rulemaking process, FDA can address the potential delay by revising the Draft Guidance to deliver many, if not all, of the benefits of a rule update.

Pfizer respectfully urges the agency to initiate a proceeding to amend the provisions of Section 202.1(e) that disserve the needs of consumers and unnecessarily restrain the speech of manufacturers. The effort should be accompanied by a call for further research on how consumers behaviorally respond to various options for disclosures, which will ensure that the agency crafts new rules based on the best possible factual predicate. The result of the rulemaking will likely be a decoupling of the disclosure mandates imposed on consumer advertising from those imposed on professional advertising. Because FDA already recognizes this basic distinction in enforcing its rules,¹⁰⁵ the formal change should not, as a practical matter, radically alter the agency's operational oversight of DTC ads.

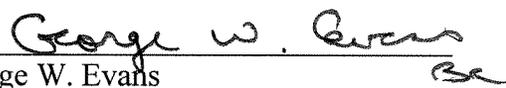
¹⁰⁵ See Broadcast Guidance at 4; Draft Guidance at lines 57-73.

CONCLUSION

Pfizer appreciates this opportunity to comment upon the Draft Guidance, and we look forward to engaging in future discussions with the agency that will lead to risk disclosure regulations that will better serve consumer needs, encourage better doctor/patient dialogue, and satisfy First Amendment requirements.

Respectfully submitted,

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EXHIBIT 1

FDA News Teleconference Announcing DTC Draft Guidances, February 4, 2004

Moderator: Now I will turn the meeting over to Miss Laura Bradbard. Miss Bradbard, you may begin.

Bradbard: Hello, and thank you for joining us at this announcement. Our teleconference will last for thirty minutes and there will be time for questions after Dr. McClellan's presentation. We're joined by Dr. Rachel Berman, Deputy Director of the Office of Medical Policy, and Mr. Peter Pitts, Associate Commissioner, External Relations. FDA Commissioner, Dr. Mark McClellan is here to tell you about FDA's new draft guidances to improve communications to consumers and health care practitioners about health conditions and medical products information. And here is Dr. McClellan.

McClellan: Laura, thank you and thanks to all of you joining us on the phone today. I am very pleased to announce these new guidances designed to improved communications to consumers and health practitioners about medical conditions and medical products. I also want to thank some of the other people on the FDA staff who are on the call, Rachel Berman and others, who worked very hard to both help conduct some of the studies that were the basis for our actions, conduct public meetings where these studies and much other science on how to communicate effectively with consumers was discussed, and then all their hard work on actually putting together the guidances. These are the results of an extensive amount of FDA research and policy development and they follow on a

conference that we held in September 2003 on how to get more out of consumer directed advertising.

We intend to do all we can under the law to make sure that the information conveyed by prescription drug promotion is as useful as possible and these new regulatory guidances provide new directions to sponsors on how to provide high-quality health information to the public within the law within the scope of providing information that is truthful and not misleading based on recent evidence on what works and what isn't working in drug promotion.

The evidence shows that promotions directed to consumers can play a particularly important role in helping patients start a discussion with their health practitioner about many conditions that are often unrecognized and are under-treated in this country. These conditions include diabetes, high blood pressure, high cholesterol, depression and many others that have been the subject of DTC advertising and, we think those discussions need to reflect a better understanding of the key risks and benefits of a product based on the results of our studies and our public comments.

According to an FDA study, most doctors surveyed believe that DTC advertising does increase patient awareness and involvement. It helps improve compliance. This study also shows that DTC stimulated visits to a physician can help identify previously undiagnosed conditions. Among the patients who visited their doctors because of an ad they saw and who asked about the prescription drug in the ad by brand name, 87% actually have the condition the drug treats, and the physicians

believe that about 80% of these patients understood the condition. So the ads seem to do pretty well already in reaching patients who may actually benefit.

Which is good, again for these under-treated conditions in this country.

Other studies presented at the FDA open meeting also show that advertising is helpful in addressing under-treated conditions. However, physicians and others have expressed concerns that patients may not have a clear picture of the risk and benefits of the treatment when they go into that discussion and that complicates having an initial conversation with a doctor. The doctor still usually gets the patient treated in the right way. In fact, in most cases, patients end up being treated differently than with the advertised medicine. But, the doctors tended to believe in our surveys that there would be benefits if the ads did a better job of communicating key risks as well as the important benefits of a product. So, that's the scientific framework for these guidances that we are announcing today. And, there are three of them. One of them provides alternatives to the lengthy and detailed and rather technical brief summary of risk information for consumer directed print advertisements of prescription drugs. And this right on the point of trying to improve consumer understanding of key risks and benefits, which I will talk more about in a minute. This may be a case where "less is more" in terms of consumer understanding.

Second, advice for manufacturers on the use of disease awareness communication, so-called "help seeking" ads, are the subject of our second guidance. These ads are designed to educate patients or health practitioners about particular diseases or health conditions. As I mentioned earlier, there is a lot of

evidence the DTC ads can help get people into the doctor for under treated conditions.

Third, the third guidance deals with advice from manufacturers on compliance with risk disclosure rules for consumer directed broadcast advertising for so-called restricted medical devices. You can think of these as major medical devices like hearing aids, contact lenses, pacemakers, that are increasingly the subject of DTC advertising, as well. We want to make sure that there are clear rules to help patients get a truthful and not misleading perception about the risks and benefits of these products as well.

I'm going to spend a few minutes talking about each of the three guidances and then we will take questions. On the brief summary guidance, just a reminder that the manufacturers fulfill this requirement typically by including the complete risk related sections of the FDA approved professional labeling. And, that's good for doctors who want to look up the precise details of a medicine in their PDR. It's not so good for patients who are pressed for time and really want information that they can easily understand and use. Risk information presented in this manner satisfies the regulation, but it is not user-friendly. So it's technically in compliance with the law in terms of providing information, containing information on benefits and risks, but it doesn't convey that information as effectively as it should to many consumers who find it too detailed and off-putting. Now, we know the consumers want useful information on the benefits and risks in the ads they encounter, we hear that all the time, but because the brief summary is the main tool designed to convey such information, we also know that

we need to do better. In our studies, we found that most patients rely on the brief summary not at all or just a little, and that's a concern since this section of the ad is designed to get the message across about key risks and benefits. So the focus of this guidance is designed to encourage manufacturers to create and deliver more user-friendly information so they can end up, as a result of the ads, being better-informed partners. They can go into those discussions with their doctors with a clear understanding of the important risks and benefits that is the best foundation for useful further discussions with health professionals.

So, we want manufacturers to present key risk information in consumer-directed print advertisements in a more consumer friendly way. And the draft guidance is very clear about a number of steps to do this. It encourages the use of clear, less cluttered formats for presenting the risk information, encourages manufacturers to focus the risk disclosures on the most important and most common risks, and we've got clear guidance on those risks for the first time, and to do so in language that is easily understood by the average consumer, and that's in the guidance and detail as well.

So, I think there are a couple of advantages here over the current system. And this is where I get to the point about "less is more". Less is more for consumers because they can actually get more out of this information. The larger type, the clearer language, the focus on the more important risks that are a basis for further discussion with the health professional, and an appropriate basis is more beneficial to them in taking something away from the ads, rather than just skipping over a brief summary section as most consumers seem to do today. In

addition, less may be more for manufacturers as well because less type and less or lower volume of information needs to be conveyed then, what can often be a full page of brief summary, small print in current advertising, advertising costs may be lower. So, it can be a win, win – getting more effective key information to the consumers, reducing advertising costs at the same time. The draft guidance also makes clear that we want to encourage manufacturers to prevent the most important risk information in the main body of an advertisement. We suggest using consumer friendly bullet point format in a risk information window inside of the text of the ad itself rather than just relying on the brief summary guidance, and we ask for further comments about all of these approaches. We want to make sure that we are doing all that we can to address what has been identified as an important problem in DTC ads working as effectively as they should to help people improve their health.

The second guidance is on “help seeking” and other disease awareness communications. As I said before, there is clear evidence that DTC advertising can be helpful in getting people in to see their health professional about conditions that can be treated today. So, we want to encourage this type of advertising in addition to the DTC ads for particular topics. This guidance clarifies the criteria that we use to identify and distinguish communications that provide information about the importance of recognizing certain kinds of symptoms being evidence of a treatable disease. This is different from the promotional messages for particular treatments. The latter do need to include the requirements I just went through about conveying accurate details about risk and

benefits, whereas help seeking ads need only focus on making sure that people understand the signs and symptoms and so can get into the doctor appropriately. That can end up being helpful for the manufacturer of the product because some of those patients will go on to be treated with a drug or other medical product that the company manufactures. As I said before, very often, even for the DTC ads targeted to particular kinds of products, patients end up being treated in a different way. So this is another complementary tool to get patients into the doctor for under treated conditions.

A third guidance that we're releasing today focuses on consumer-directed broadcast advertising for restricted devices. As I mentioned, I think of restricted devices as the major medical devices; more minor medical devices such as band-aids are regulated by the FTC. These products are increasingly being advertised and so, for the first time, we're providing clear and specific guidance to the industry on how to convey risk disclosure information in these ads. Again, with the same goal of making sure that all types of ads – both print and on-air ads for medical devices get across the key messages about risks and benefits. So, we track the same kind of guidance that we provided in the past for prescription drugs and this gives us a more comprehensive, a very science-based approach to regulating all types of promotion.

By putting out these guidances, we believe that evidence-based regulations as a result of these guidances will help FDA use its limited resources to police the marketplace as effectively as possible. And backed up by even more specific information about how manufacturers – steps they need to take to comply with the

law, we want to make clear that we will take action against sponsors whose ads violate the law by presenting false or misleading information to the public.

Conversely, we want to work constructively with manufacturers to help to make sure patients get as much as possible out of the DTC ads. So, there is a piece of this that helps with our enforcement effort, helps target them more effectively, and a piece of this that helps hopefully improve the quality and the utility of prescription drug ads and other types of medical product advertising to benefit the public health. We should be clear that if these guidances and if our regulations aren't followed, we now have an even stronger and clearer basis for pursuing enforcement action.

I am pleased that we've had help in this effort not just by FDA's professional staff, not just by the commenters from various public and private organizations in the context of our recent workshop and conference on this topic, but also we are working closely with the Surgeon General's Office on this effort. Health literacy is a critical goal of the Surgeon General because there is just so much today that people can do, through their own choices, through using the latest scientific information to improve their health. And, as Surgeon General Carmona stated in our press release, he believes by closing the gap between what doctors know and what patients understand is a start and further their conversations about how to improve their health, we will be able to help Americans take better care of themselves.

All of these documents are available on our website along with a Press Release and we are asking for comments on these documents because this is an issue

where we want to make sure that we're keeping up with the latest science and taking account of all of the perspectives out there on how to make advertising (which is here to stay) as useful as possible for consumers. These documents are also a key part of our strategic plan. Just as Surgeon General Carmona believes that getting good information to consumers is an essential part of improving the health of the public, it is a key element of FDA's own Strategic Action Plan, which has a particular goal focused on creating better-informed consumers.

I'm going to stop there, I want to thank you all for joining us and for listening to me explain some of the basic features of these important new guidances and I think we would be happy to take a few questions at this point.

Moderator: Thank you, we will now begin the "Question and Answer" session. If you would like to ask a question, please press *1. You will be prompted to record your name, to withdraw your request, press *2. One moment please... for the first question.

Mark Kaufman of the Washington Post – you may speak your question:

Kaufman: Well, in terms of the first new guidance, is there anything there that will be involved with television advertising? It seems it was mostly written, print advertising that you were referring to there.

McClellan: That's right, Mark. The brief summary is required on print ads. As you know in the broadcast advertisement, the key risk information must be conveyed in the body of the advertisement itself, and this guidance does not go that particular

aspect of broadcast ads. We, of course, remain interested in reviewing the evidence and finding ways to make sure that broadcast ads convey appropriate information. The other two guidances that we released today do pertain to broadcast ads. We want to encourage, where possible, accurate help seeking ads. That's something that I think can be done effectively for broadcast mechanisms and we want to make sure we've got clear regulations in place to govern and clear guidance in place to govern the appropriateness of broadcast ads for devices. So those other two guidances do pertain to broadcast, but the first one on that brief summary is really about the brief summary in print ads.

Kaufman: If I could follow up In terms of the effect of broadcast ads, there has been a lot of discussion about how, in addition to bringing people who need help to doctors, they sometimes encourage the overuse of drugs. Does that play a role at all in your

McClellan: Mark, we reviewed the evidence on the effect of all types of advertising as part of this conference back in September and there was a fair amount of discussion around the benefits and potential problems of broadcast ads there. So I'd refer you back to that Rachel may have something more to add here. I think the main conclusion from all of that discussion was that the ads do get people in to the doctor and, for the most part, as I mentioned earlier, they are coming in with the condition that was intended to be treated by the product that is advertised. So, that's all good from a public health standpoint. Doctors have expressed some concern, as I stated earlier about patients not having a good sense of the key risks and benefits, some of the important limitations of a treatment, and that's why we

are doing this guidance, to help make sure those come across in the print ads effectively. We already require the key risks to be stated explicitly in the broadcast ads, and we have a lot of regulatory enforcement structure in place to help make sure that that information is conveyed effectively, and we will remain vigilant to see if there is evidence that we could change our guidances while staying within the law, which does allow direct-to-consumer promotion to make sure that it's truthful and not misleading. A real focus here though is on making sure that patients get a key sense of the risks, as well as the benefits, as they go into those conversations with their doctors.

Kaufman: Thank you.

Moderator: Donna Young of AJHP, you may state your question.

Young: Yes, thank you. Dr. McClellan, why did you not update any of your guidance on broadcast ads and also with the number of enforcement actions that you've initiated in the past year for false and misleading advertisements, how many of those were for print ads and how many of those were for broadcast ads?

McClellan: I don't know the numbers on print vs. broadcast. Rachel do you have that?

Berman: The vast majority were for print.

McClellan: Right. Some were for broadcast. Some significant ones were for broadcast as well and we can get you more details on that information. I think it is also available on our website. Both of those types of ads are subject to our regulatory oversight, and I want to emphasize that we are trying to take a very

comprehensive and proactive approach to getting the most useful information to consumers out of DTC advertising, and that's why one part of what we do is untitled letters and warning letters. But, we also want to provide very clear guidance about what is in and out of bounds. Broadcast and print ads do not run for that long and I think we can have a far more effective enforcement strategy that's not based just on "whack amole" trying to get after all the ads that are out there without providing clear guidance for what is and is not out of bounds, but rather providing as much guidance as possible up front so that responsible companies will comply and so that we can focus our limited resources in the cases where there are real problems. And you have seen us take this kind of approach with promotion more generally. FDA has done more in the past year than ever, for example, on enforcement actions against dietary supplements making misleading claims, several times more warning letters on those products over the past year where health benefits were claimed, risks were not presented, in a way that was not based on science, and other types of enforcement actions as well. Product seizures, fines have been involved in other kinds of legal actions too. So, there is comprehensive strategy here for getting to effective enforcement. I think an important part of that is providing very clear guidance about what's in and out of bounds.

Young: And my other question is about why they didn't include broadcast in these draft guidance?

McClellan: We felt that the top priorities, based on our discussion at the September meeting were first, getting more utility out of brief summary which, as you know, most

promotion is in print and that is also an opportunity to give people more information about risks and benefits where we're falling short of the opportunity. So, that was priority No. 1. We also heard a lot about the potential value of help seeking ads and we want to provide a clear path for those ads too and we also heard concerns about broadcast ads for devices where no guidance was in place. So, those are our top priorities. We will obviously keep working to make sure that broadcast ads for prescription drugs convey accurate information as well, very much in line with the goals that we've outlined for these three guidances today.

Berman: It's also worth noting that in a broadcast ad it is much easier to follow the "less is more" philosophy. It's very short and, in general, the ads do a better job, if you will, of emphasizing just the key important points in a way that is very understandable and in a way that the information can be easily retained. We have, there was a significantly bigger problem in print.

Young: So are you saying that there's not a need for updating the draft guidance for broadcast?

McClellan: What we are saying is that these guidances focus on what we thought were ways that we can – we've got limited resources at the FDA and we need to use them as effectively as possible, based on what the science has to say about how we can improve the public health. So these three guidances were our top priorities and that's why they are out today. We are going to keep looking at the science and the evidence on ways to help get accurate information to consumers in all types of

ads including broadcast ads. So, this is certainly not the last word from FDA on this important topic.

Bradbard: May we have the next question please....

Moderator: Rich Thomaselli, you may ask your question.

Thomaselli: Thank you. Good morning Dr. McClellan. Quick question or almost a follow-up to some of the broadcast advertising. Pharmaceutical companies have already said that if unbranded or help seeking messages were part of the new guidelines that they would jump in right away and do some unbranded spots, but also some said that they would also do these spots, for instance if they had an ad budget of, you know, five spots for Brand "X" for the entire year, that they would do four spots, and the fifth spot would be an unbranded ad. Does it matter to you how these spots get into television. Whether they increase their advertising budgets to do this or simply borrow from their current existing budgets and just reduce some of their branded spots and add in an unbranded spot. Does it matter to the FDA just as long as

McClellan: Well, I can't dictate to the company how they spend their advertising budget, that's their decision about their advertising. What we can do is make clear what the regulatory requirements are and also provide pathways where we think that more useful advertising could be provided. It's advertising that conveys risks and benefits more effectively, advertising that focuses on help seeking and that's what we are doing today. So, I don't know how they are going to change their advertising budgets. I do know that, based on our review of the science and our

discussion with the public, these are steps that FDA thinks will help improve the public health.

Bradbard: May I remind people to please give your publication or affiliation before you ask a question.

Moderator: Reginald Ryan of Script World Pharmaceuticals, you may ask your question.

Ryan: Thank you. I'm interested in whether you're taking care of the problem that was evident a while back on the delays that sometimes happen between a bad ad on television and a warning letter being sent out to the company because it had to go to the general counsel's office?

McClellan: We're working as best we can to streamline our process for getting out letters that are consistent, and that will stand up effectively in court, and that will be the basis for further enforcement action. And we will continue to do the best we can in that regard. I do want to emphasize though that letters are not the only part of an effective enforcement strategy. Because advertisements typically do not run for that long, we can get more mileage out of providing clear guidance upfront and taking further steps to encourage companies to comply with the law; with limited resources and short time frame for ads, that's also an effective way to encourage appropriate promotion.

Ryan: Thank you.

Moderator: John Wilkerson of FDA Week, you may ask your question.

Wilkerson: Can companies already do DTC ads for restricted devices and, if not, are they going to be allowed to now?

McClellan: They are already doing ads for restricted devices and when they run these ads they have basically FDA's general past experience to guide them in what is in and out of bounds. We have not done a specific guidance on how to convey risk and benefit information, how to assure that the ads are truthful and not misleading for this increasingly common type of broadcast ad. Rachel may have more to add on that.

Berman: Yes, that's right.

Moderator: Cathy Hollingsworth of BNA, you may ask your question.

Hollingsworth: Yes, Cathy Hollingsworth with BNA. I wanted to know if you could elaborate on what you said towards the end of your opening remarks. You said that if companies don't follow the new guidances, there are stronger actions that FDA can take, and I wanted to know what those stronger actions would be.

McClellan: Well, we do have other enforcement tools, including warning letters and pursuing further legal action, if appropriate. In some cases of fraudulent promotion over the past year as well, we've worked with the Office of the Inspector General, other law enforcement agencies, and when kickbacks are involved or other types of truly misleading promotion to bring criminal actions, and sanctions and fines. So there is a whole array of tools that we try to use with our limited resources to have the most impact on the most misleading types of advertising and providing

clear guidance as well. The expectation is that by providing more clarity about what ads are in and out of bounds and, as with this device broadcast ad guidance for example, we will get more compliance from companies that want to be within our regulations and that will help us focus our enforcement efforts on the bad actors, where there is necessary further steps to get compliance.

Hollingsworth: If I could just follow up on that, this is related to this question.

Congressman Waxman has complained about the FDA's actions not being stiff enough or tough enough and I was wondering if the FDA is considering taking stronger action as far as repeat violators in broadcast or in print.

McClellan: Well, we're certainly considering further actions along those lines, but in terms of enforcement, we have stepped up our across-the-board enforcement activities on many types of promotion and other stuff that companies take to inappropriately encourage use of their product in many ways. If you go to our website, we have a report on enforcement actions as part of our consumer initiatives of 2003, that reviews the substantial increase in our actions against dietary supplements making misleading claims, that reviews our criminal actions, fines and the like against fraudulent types of promotion. So there is a comprehensive approach here that uses the most effective tools possible to get appropriate promotions.

Berman: But it's also important to remember these are guidances that are supposed to help companies to comply with existing regulations.

McClellan: Right.

Berman: So that, for example, a brief summary as you did earlier, that is a verbatim reproduction of the risk information from the professional labeling, is in compliance. And in fact, we know from our studies that more than half of people will read them but, as you said, they don't rely on them because they can't get useful information out of them. These are ways to help companies present the information in a more useful manner. It's somewhat... not addressing necessarily something that's false and misleading, but rather being a more useful communication tool. Similarly, risk information is already required in the body of the advertisement. But it should be acceptable and understandable and useful. Because, again, if you mention when that patient goes to the physician to discuss the medication it is not that it promotes additional or inappropriate use of drugs, but rather it promotes a discussion of what disease they may or may not have that they may or may not have recognized and what therapy may or may not help.

Bradbard: We can take three more questions and then we'll have to wrap it up.

Moderator: Monica Conrad of ABC News, you may ask your question.

Conrad: Good morning.

McClellan: Morning.

Conrad: You say there is clear evidence that the DTC ads can be helpful. Now is that just print, I'm coming back to broadcast here. What does the evidence say about broadcast ads?

McClellan: The evidence is similar for broadcast ads. Many of these ads target conditions that are under-treated in the population. I mentioned diabetes, depression, high blood pressure, conditions like that, and they do, studies show, get people into see their doctor.

Conrad: And about enforcement. Again, it's Waxman came out with something recently that said the amount of enforcement letters or enforcement action, I can't remember the numbers, dropped dramatically since 1999. Are you comfortable with those numbers?

McClellan: Well, he's right that the number of letters have been steadily declining since in the 1990s. It's not any sort of cut-off at the year 2000 or 2001.

Conrad: He looked at it from 1999, I think, to present.

McClellan: If you look at the actual numbers and we've had some correspondence with Congressman Waxman on this before, sent him a letter, and going over the year-to-year trend, and again, I would emphasize, and go to our website, see a lot of other enforcement actions that we are taking as part of this comprehensive approach to try to get advertising right.

Conrad: Well, it's just, and with the numbers dropping off, it seems to suggest that enforcement isn't where you're putting, as you say, your resources, your limited resources at the FDA.

McClellan: Well, we want to make sure that the enforcement letters we do send out will deter behavior, that they are going to stand up in court and that's where our review bar

chief counsel really helps in getting consistency and clarity and a firm legal basis for further enforcement action as appropriate. But letters are by no means the only enforcement tool that we have. We have guidances, we have interactions, other kinds of informal interactions with companies that try to get them to do the right thing in the first place, and we have other enforcement actions that we can take as well.

Conrad: And just one more follow-up. There seems to be criticism of it taking far too long for these enforcement letters or warning letters to get through your chief counsel's office. Is that something that you're looking into? Is that something that you guys notice....

McClellan: We always want to do, we always want to take the steps that we can to make our enforcement efforts work as efficiently as possible and that is why we are making the announcements today about clear guidances for how to comply with our regulations and how to convey useful information to consumers. I do think that with these guidances, backed up by FDA's efforts to reach out to companies, and FDA's making clear that we will enforce the law, that we will get more compliance with ads that provide useful benefit and risk information. To get patients into their doctors appropriately and it provides public health benefits that I've outlined.

Conrad: OK. Thank you.

Moderator: Julie Appleby of USA Today, you may ask your question

Appleby: Hi. Thank You. Could you tell me how this new guidance might affect some of those ads that we see on TV that, I don't know, they just show a pretty little picture or something like that and then it says, "Ask your Doctor" and it has the name of the drug and you have no idea what the drug is for or what it does or any of the risks or drawbacks. Will this affect that type of broadcast ad?

McClellan: I'm going to let Rachel talk about that. I believe you're talking about reminder ads, and reminder broadcast ads for drugs are not part of the guidances that we released today. Our guidances, again, focus on all print ads for drugs, focus on help seeking ads that talk about a condition or symptoms or signs of a disease that you may have, and broadcast that for devices.

Berman: If a company makes a claim about their drug, they say that it does "X", then they have to balance that with appropriate risk information. A reminder ad simply reminds the audience that the drug exists. That is not required to be accompanied by risk information. If, however, the help seeking guidance is used with, and I need to talk about this, if a reminder is linked somehow with a help seeking ad, that might constitute, together, a drug ad which would then need to be balanced by risk information and again, instead of trying to encourage companies to do more help seeking ads, which we think are important from a health point of view, we wanted to be clear on when they do and do not need to include such risk information.

McClellan: Now that's an important point in press release. We talk about this sort of book ending process that we want to make sure does not happen inappropriately, where

a reminder ad like the one you described is placed next to an ad for help seeking that really would make clear, that could imply to consumers that here's a drug that could be used in a particular condition without conveying the risk as well as the benefits clearly. And we do have guidance on that.

Appleby: So back-to-back would be one right after another or could it be in the same broadcast show or...

McClellan: The guidance goes into where we would have concerns and it's broader than just one right next to another.

Appleby: OK. Thank you.

Bradbard: Now one more question please. Dr. McClellan has to go on.

Moderator: Our final question comes from Jill Wexler of Pharmaceutical Executive Magazine.

Wexler: Do you expect that drug companies are going to be active in using these new modified formats for conveying risk information in print ads before you have the final rule on professional labeling that spells out this summary approach, Highlights approach, for revising the labeling?

McClellan: We are providing clear guidance about the key, the important risks and benefits now so that companies can go ahead and we certainly are going to be looking to see what happens as a result of this guidance being out there. We do want to encourage more effective communications about key risks and benefits and this is

a draft guidance, it is subject to further revision based on public comments and based on our experience about how it works. So, I do think that we can see some progress right away, before the final physician labeling rule is out, but we will keep looking at this until we do get more effective risk and benefit information communicated in the print ads.

Bradbard: All right, thank you very much. If you have any other questions, please call the FDA press office, (301) 827-6242. Thank you.